Regulatory Management and Leadership Strategies

Top Leaders Discuss Mindset, Mentoring, Ethics and People Skills

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Regulatory Management and Leadership Strategies

By Gloria Hall

Welcome to the third edition of the 2019 *Regulatory Focus* Article Series. Inside you will find a collection of insightful articles covering regulatory management and leadership strategies plus five candid interviews with global regulatory experts. It is a pleasure to bring together some of the top regulatory influencers from around the world—all with diverse experience—to offer their perspectives on career development in the regulatory profession.

Leadership Skills

The past few decades have seen an exciting evolution in the regulatory profession. Increasingly complex products, corporate structures and regulatory environment have created a demand for highly skilled regulatory leaders. Their roles have enhanced in importance and stature over the years and have now been recognized as a key strategic role. Many are now represented at the C-suite levels in the organizations. In "Critical Thinking and Leadership Skills for Regulatory Professionals," retired regulatory executive **Robert Yocher** presents various sets of often underemphasized skills required for a successful regulatory professional career. Every person at every level can use them every day.

Professional Development Strategies

Many national governments today have policies in place to foster growth of the medical technology and biopharmaceutical industry to contribute to the new knowledge economy. As the industry grows, organizations continue to face increasing pressure to find and retain talented and suitably qualified staff across a range of functions involved in the discovery and development of new therapeutics. In "Professional Development: Benefits of Obtaining Professional Qualifications," associate professor **Orin Chisholm** discusses the advantages of formal qualifications for a regulatory career and highlights some of the English-language Master's-level courses offered globally.

Team Management

An initial marketing application submission is a major undertaking requiring a large team, numerous tools and a litany of subprocesses working in harmony for a successful outcome. Leaving any of this to chance is likely to result in missed timelines and excessive "crunch time." In "eCTD Submission Management," regulatory operations manager **Ryan McNeely** explains how with thorough planning, careful execution and the ability to navigate unexpected challenges, the odds of success can be greatly improved. This high-level walkthrough will raise important considerations when planning an electronic Common Technical Document (eCTD) submission.

REGULATORY FOCUS

Career Transition

The decision whether or not to take a career break can be an agonizing one, and there are many challenges one might face going back to work after a long absence. In "How I Returned to Regulatory Affairs After a 10-Year Break," regulatory professional **Olivia McBride** lays out steps for regaining your career and suggests ways to negotiate terms that could help create an easier and more successful transition when making your return.

Making the transition to any new job—regulatory or otherwise—can be challenging. Hear some helpful advice from regulatory veteran **Steve Jwanouskos** on how to make the move more smoothly and effectively. "Making the Switch to Advertising and Promotion: My First 90 Days" provides some simple steps to follow in your first 90 days on the job and ease the job transition.

Career Development

Is an inquisitive person more likely to be hired? Hear **Max Sherman**'s perspective in "Curiosity: One of Life's Most Valuable Commodities." Regulatory expert Sherman takes an interesting look at the value in human curiosity for learning, living a more meaningful life and as an important tool for professional success. He reviews several books on curiosity outlining why we are curious, explains different types of curiosity and suggests how we might not lose our curiosity as we age.

'Focus on' Interviews

Also included in this series are five 'Focus on' interviews where we talk with regulatory leaders, thinkers and influencers, sharing their thoughts on a range of topics. In this series, we not only discuss healthcare, regulation and the regulatory profession, we also look for unique personal insights and perspectives. Here's a recap of what you will find inside this series:

Don Boyer, RAC, FRAPS, spent more than 30 years at Health Canada, including serving in several senior management positions, before leaving Canada's regulator to start his own regulatory consulting firm. In January 2019, he began his term as chairman of the RAPS board of directors. Don shared his vision for RAPS' growth and evolution, talked about the trend toward specialization in the regulatory field and stressed the importance of maintaining a problem-solving mindset.

Jethro Ekuta, DVM, RAC, FRAPS, is an active RAPS volunteer leader, having served in various roles including chair of the RAPS Fellows Selection Committee and as a member of the Regulatory Affairs Certification Board (RACB). He recently completed his term as president of the RAPS Affiliate Board, currently sits on the RAPS board of directors and is the board's incoming president-elect. Jethro shared his thoughts on the importance of being open minded, helping people reach their potential and why he is so passionate about regulatory affairs.

Minnie Baylor-Henry is the president of her own consulting firm, B-Henry & Associates. Previously, she served as one of Johnson & Johnson's top executives and as a national director for regulatory and capital markets consulting with Deloitte & Touche. Minnie was also with FDA as national health fraud coordinator and director of FDA's Division of Drug Marketing, Advertising and Communications. She is active with RAPS and has led several RAPS workshops for aspiring regulatory leaders. Minnie shared her thoughts on leadership, mentoring and diversity.

Bill Sietsema, PhD, has 35 years of experience in the pharmaceutical industry and is currently vice president of global regulatory affairs at Caladrius Biosciences. He has published six books on regulatory topics, and served as editor of several RAPS publications, including *Global Pharmaceutical and Biologics Regulatory Strategy* and *Risk Management Principles for Devices and Pharmaceuticals.* Bill shared his thoughts on what it takes to be a good regulatory professional, the importance of ethics and what else he might see himself doing if he weren't in regulatory.

Allison Komiyama, PhD, RAC, began her regulatory career at FDA as a biologist and reviewer and later served as lead reviewer and consult on 510(k) premarket notifications, investigational device exemption (IDE) applications and premarket approval (PMA) submissions. After FDA, Allison worked on the industry side in senior regulatory roles before starting her own consulting firm, AcKnowledge Regulatory Strategies. She holds

the Regulatory Affairs Certification and has served as a content expert for RAPS. Allison shared her thoughts on new technology, the importance of people skills, and how regulatory affairs is like rowing and more.

While these short summaries were meant to pique your interest, we hope you spend some time reading the complete articles and benefit from the shared experiences of our authors. This collection was meant to give you the information needed to enhance the skills necessary for a satisfying, successful career in regulatory as well as provide strategies for continual professional development. Your feedback is always welcome.

Gloria Hall is RAPS senior editor responsible for volunteer contributed feature articles for Regulatory Focus. She can be contacted at ghall@raps.org.

Critical Thinking and Leadership Skills for Regulatory Professionals

By Robert E. Yocher, MHSC, FRAPS

This article presents the opinions of a retired regulatory executive on the various sets of often underemphasized skills required for a successful regulatory professional career. Every person at every level can use them every day.

Introduction

The past few decades has seen an exciting evolution of our profession. Increasingly complex products, corporate structures and regulatory environment have created a demand for highly skilled regulatory leaders. Their roles have enhanced in importance and stature over the years and have now been recognized as a key strategic role. Many are now represented at the C-suite levels in the organizations.

Most (but not all) people entering the regulatory field have a medical, science, engineering, math, computer or legal backgrounds. Scientific backgrounds are helpful to understand the products, their effects and intended uses. Legal backgrounds are helpful to understand statutes, policies and regulations. Math and computer skills are very useful for the complex software and analytics, which are becoming increasing vital to our industries.

However, with today's internet and instant information you can find regulations, medical terms and statistical help with a few keystrokes or specialized apps. Deep technical skills alone do not prepare you for growth within the organization. Reliance on more general skills take precedence the higher you go in an organization. These skills must be learned and practice. Critical thinking and leadership skills may be more important to be successful today. These skills are often overlooked and must be learned and practiced from hiring to retirement. They are a foundation for the executive skills sought by a corporation. People who have these skills are readily recognized and rewarded at all levels.

What is critical thinking?

In a 1941, seminal study on critical thinking skills by an educator named Edward Glaser critical thinking skills became better known.[1] He stated, "Critical thinking generally requires ability to:

- recognize problems
- find workable means for meeting those problems
- gather and marshal pertinent information
- recognize unstated assumptions and values
- comprehend and use language with accuracy, clarity and discrimination
- interpret data
- appraise evidence and to evaluate arguments
- recognize the existence (or non-existence) of logical relationships between propositions
- draw warranted conclusions and generalizations
- test the conclusions and generalizations at which one arrives and
- reconstruct one's patterns of beliefs on the basis of wider experience"

This is the essence of what a regulatory professional does. Glaser's definition reads like a job description. They can be reduced to questioning, interpretation and communication.

Basic Critical Thinking Skills

Questioning, Interpretation and Communication

Questioning is perhaps the quintessential act of critical thinking. Question everything. Do not take information on authority until you investigated it personally. Finding the answer is what critical thinking is all about. Use active open sentences and use sound investigative tools such as the five whys, the is/is not or other inductive or deductive tools. Check for objective evidence and evaluate the sources of information and its reliability. Questioning is fundamental to understanding he problems, its solution, its implementation and its acceptance.

"Interpretation is the ability to analyze and understand the information you are being presented with and being able to communicate that to others."[2] Whether complex regulations or abstract medical concepts, regulatory professionals are asked to interpret data constantly. The ability to connect pieces of information together to determine an accurate conclusion from the information available and clearly explain this so as to be understood by the various intended audiences is critical throughout your career.

Communication skills are key to achieve the two previous skills. Although under-emphasized by many educators, your interpersonal actions, presentation, writing and negotiating skills are needed from novice level through the executive level. These get better with practice but they are critical to advancing your career.

Leadership Skills

Gene Wade once said "Leadership is not what you do; it's what others do in response to you."[3] Think of the difference between a boss and a leader. A boss is someone who orders you to follow and a leader is someone you want to follow.

A huge industry is devoted to leadership development with over 120,000 books on "leadership" appearing on Amazon. The academic research on leadership has coalesced around a few broad areas of vision creation, planning, networking, good decision-making, and influencing. Let's examine these areas more closely.

Leaders Often Share a Vision

Jesse Stoner Zemel once said, "A vision is a clearly articulated, results oriented picture of a future you intend to create. It is a dream with direction."[4]

Leaders win followers by creating shared focused beliefs and in turn effect change. Commonality, synergy and alignment to accomplish goals lead to success. Very few things are accomplished alone. This can be demonstrated at the team level in everyday work or

in the boardroom. To help achieve this vision, you should understand what excites and energizes your teams or followers. Develop a well-articulated, compelling story. Visions should help people better understand how their jobs contribute to the success in reaching those shared goals.

Good Leaders Build Plans

They ask others advice in their areas of expertise. They often create small but powerful teams. They clarify roles and responsibilities and identify behaviors critical to success. After meeting with the team and giving recognition to the people who strive for excellence, identify and fill any voids. Then they write and share the plan to effect the change to reach the vision. Clearly written plans with specific actions, agreed upon roles, responsibilities and behaviors are key to achieving success.

Leaders use and Develop Networks

Networks are something vital throughout your career. Networks could be formal or informal. They could be co-workers (horizontal and vertical) colleagues or even customers. Networks are great resources and often help effect change management. They often help identify key stakeholders and the political landscape. They may aid in developing structure and systems, which may be needed to overcome concerns of negative skeptics avoiding potential escalation. Leaders often use their networks to provide intelligence or utilize them as promoters or sponsors. They often also are a resource to help create or promote community and culture.

As a professional grows within the organization, there will be less a less specific technical knowledge and more and more need for general management and business knowledge. Effective leaders are expected to know what is going on in other parts of the company and the industry. They need to bring cross-functional knowledge to bear on issues and opportunities outside of just regulatory. Few issues at the executive level concern just one department but the company and all its stakeholders. Effective leaders make it their business to develop a wider view of the company, industry and the environment in which it must thrive. Leaders need to develop cross functional or cross disciplinary knowledge as well as maintaining good working relationships with peers who have expertise in other areas. To develop understanding other disciplines consider the following:

Learn the business from the perspective of the functional areas by asking:
- How they see the business and learn how that might be different from yours.
- What are their goals and strategies and learn their importance to the business.
- Who are their customers and what are their customers needs expectations and/or challenges.
- What are the metrics and why. Metrics typically point out critical variables that underlie important business processes.

Wherever possible seek out assignments in different functional areas or work on teams outside regulatory. Networking should start as early in your career as possible. Make your supervisor aware of your desire to network and why. Make it a point to eat lunch with a networked person at least once per week if possible. The networked resource is one of the most valuable tools in you toolbox and a strong indicator of your executive talent development.

Influencing

The last part of leadership is influencing. Good leaders influence by fostering collaboration within their teams and their networks using mutual respect for others knowledge and opinions. They build trust by being open to competing thoughts and expressing a desire to finding mutual solutions. They take time and effort to understand the other party's reality made up of personal characteristics past experiences, cultural and family influences, work environments, value systems, time constraints, motives, needs and goals. This understanding is a vehicle for helping us to determine what is important and unimportant to others. This allows for us to negotiate a solution and make better decisions. How do we do this? It goes back to our old friends discussed in critical thinking. Leaders

who successfully facilitate the interactions of others ask questions that spark lively discussions, listen well, invite reactions, build on other people's ideas and navigate group discussions to agreement and shared decisions. They encourage the involvement of others. When group members interact, the resources of all members are used most fully and problem solving is promoted.

To influence others, it is best to spend some time get to know one another. Different things persuade different people. Knowing what feelings, values and perceptions your audience has is vital to understanding their agenda, needs and concerns about your message. Ask why they see things differently. Seek to understand the others point of view before you explain yours. Summarize what you hear until the other person agrees that you understand what he or she thinks and feel. Build on areas of agreement before addressing disagreements but clearly state your desire to find a solution mutually agreeable. Use open-ended questions and be willing to modify your position as you learn relevant information you may not have considered. Use shared values or common ground and try to connect to your proposals. Respect the roles of others and recognize and acknowledge the worth of all parties. Treat all parties with respect regardless of level or position, with dignity, civility and courtesy. Share what you know in a non-intimidating way. Deal with emotions. Do not ignore them. We all have them. Try to focus on the issues and not the personalities. Be tolerant of and encourage those who do not initially understand. Create a positive environment encouraging participation of all parties without embarrassment, ridicule or hurtful actions or inactions. Positive behaviors that build trust, openness and a sense of fairness are seen in every good leader.

Others may help support a leader (and at the same time possibly demonstrate their own leadership) by participating. If you do not know what to say, ask a question. By asking a clarification question, like please tell me more about X or could you please give me an example? you invite the other person to share more information, so that you can fully understand his/her message. Questions are powerful. Questions can convert resistance to acceptance or turn confusion into clarity. Questions could be used to determine underlying strategy. By asking questions about implications of actions, you are demonstrating that you are considering the big picture.

Some strategic questions might be:
- How does this fit within our stated mission?
- Will our actions have any untoward effects?
- Will our actions set a precedent?
- Have others used tried this and what was their outcome?
- What metrics are important?
- How do we measure success?

By asking questions others may feel more comfortable in participating and collaborating. To have the most effective problem solving, the most flexible workforce, the open sharing of thoughts and ideas is necessary. It helps develop the culture of collaboration. Peers will open up if they see frank discussions free of intimidation.

If you are participating over the telephone, it is often disconcerting if there is a silent listener. Using fillers are a good way to support and signal that you are listening. The following are some examples:
- That makes sense.
- I understand.
- Okay.
- I agree.
- Interesting.
- Really?
- Am I a correct in that…? (Restating the key point).
- Paraphrase what you heard.

Active listening skills with the use of fillers help the leader and show your leadership at the same time. You may have seen the posters that say, "Listening is not the absence of talking but the presence of attention. Listening is not just simply hearing but

understanding." Without listening, leaders cannot effectively face the challenges in today's complex business environment. Listening goes hand and hand with questioning.

In today's environment of speed and complexity, a directive single strategic leader at the top of the organization may no longer be the most effective way to run a business. The truth is inspiring leaders are needed at every level of an organization. Corporate leaders must possess certain fundamental skills. Deep technical skills alone don't prepare us for growth within the organization. Reliance on more general skills take precedence the higher you go in an organization. These skills must be learned and practiced. Just like an athlete daily exercise will bring "muscle memory." They will give you a strong foundation in which to grow and likely be recognized by your peers and your superiors. Every person at every level can use them every day. You can exhibit these skills on a micro or macro level. You must go beyond being the subject matter expert. Create visions. Formulate plans. Network. Influence. Ask questions, listen more than you speak, seek advice from others. Observe the behavior of good leaders in and outside your organizations. You will most likely see the leaders you observe will draw their power not from their position or rank but from their ideas or behaviors. Most likely they will exhibit skills talked about here.

References

1. Glaser EM. "An Experiment in the Development of Critical Thinking." Teacher's College, Columbia University. 1941. https://www.criticalthinking.org/pages/defining-critical-thinking/766. Accessed 25 July 2019.
2. Leadership and Management. Identifying Good Managers Through Leadership Competencies. TrasDeng website. https://trasdeng.wordpress.com/leadership-management/. Accessed 25 July 2019.
3. Boldebook J. "The Power of Motivation: A Few Words From Zig Ziglar." 4 December 2012. http://www.cbcads.com/power-of-motivation-zig-ziglar/. Accessed 25 July 2019.
4. Tilus G. "6 Critical Thinking Skills You Need to Master Now." 11 December 2012. https://www.scribd.com/document/300610156/6-critical-thinking-skills-you-need-to-master-now/. Accessed 27 July 2019.

About the Author

Robert E. Yocher, MHSC, FRAPS, holds a master's degree in health science in public health microbiology and epidemiology from the School of Allied Health, Quinnipiac University. He retired as SVP regulatory and quality from HeartWare International in 2015. Prior to that, he was corporate vice president regulatory affairs and corporate compliance at Genzyme Corp. from 1999 -2010. Yocher was elected a Fellow of the Regulatory Affairs Professional Society (RAPS) in 2008 and a senior member of the American Society of Quality in 2005. He has more than 50 years of experience in the medical products business. Yocher was an adjunct faculty to the RAPS Executive Development Program at the Kellogg Business School, Northwestern University. He is also on the regulatory affairs advisory board for the School of Medicine and Allied Health at the George Washington University. He can be contacted at byocher@gmail.com.

Focus on: Don Boyer

By Zachary Brousseau

Don Boyer, RAC, **FRAPS,** spent more than 30 years at Health Canada, including serving in several senior management positions, before leaving Canada's regulator to start his own regulatory consulting firm. Earlier this month, he began his term as chairman of the RAPS board of directors. Don is a leader in the global regulatory community, and has been active not only with RAPS, but also with organizations such as the Global Harmonization Task Force and International Medical Device Regulators Forum. He holds the RAC credential and is a RAPS Fellow.

I recently had the opportunity to interview Don for the *Regulatory Focus* series, 'Focus on…,' where we talk with regulatory leaders, thinkers and influencers, sharing their thoughts on a range of topics. In this series, we not only discuss healthcare, regulation and the regulatory profession, we also look for unique personal insights and perspectives. In this interview, Don shared his vision for RAPS' growth and evolution, talked about the trend toward specialization in the regulatory field and stressed the importance of maintaining a problem-solving mindset.

Following is an edited transcript of my interview with Don Boyer:

Q **As you take over as chairman of RAPS' board of directors, what is your vision for RAPS in 2019 and beyond?**

A First, I am committed to the strategic priorities established by RAPS and endorsed by the board of directors. They are critically important and I encourage all members to read them on the RAPS' website. I consider advancing these priorities to be one of my primary functions as chairman, and a key responsibility for the entire board.

My vision for RAPS includes continuing its evolution as a truly international organization in support of regulatory affairs professionals around the world. To this point, I consider enhancing RAPS' footprint in Europe to be essential. 2019 will be an important

year as we launch the RAPS Regulatory Conference Europe in Brussels in May. It will be important for RAPS, and a priority for the board, to deliver a first-class conference which meets the needs of all regulatory professionals, with a focus on emerging issues in Europe. Needless to say, the content of this conference will be rich and rewarding given the EU's new Medical Device and IVD Regulations, the situation with Brexit and the impact they have on the regulation of, and market access for, all healthcare products. Additionally, supporting the establishment of chapters and local networks in Europe will be important in expanding the "grass-roots" network among regulatory professionals.

Secondly, my vision for RAPS includes being the premier organization for regulatory education and training. RAPS must remain nimble and flexible in the way it offers these services. It needs to provide up-to-date offerings in response to emerging issues, and do it in the ways members want to receive them. While face-to-face opportunities still have an important role, RAPS needs to continue to explore innovative ways to deliver relevant training and education.

Q   **What impact has RAPS had on you?**

A   The biggest impact that RAPS has had on me is giving me the opportunity to meet and interact with so many experienced and knowledgeable regulatory professionals. As a career regulator in an organization with many members from the industry side, the opportunity to get different views on regulatory initiatives and issues has been invaluable. There is no doubt that over the years, conversations I've had with fellow RAPS members have influenced my understanding of issues and helped me bring a broader perspective to the development of positions, policies, processes, etc., during my time working at Health Canada.

Q   **How has the regulatory profession evolved and changed during the course of your career?**

A   The biggest change that I have witnessed is the opportunity to specialize within the profession. In the early days of my career, regulatory professionals often would cover a wide array of products—drugs, biologics, medical devices, etc.—as well as various aspects of the product lifecycle, including premarket, postmarket, GMP and QMS. Nowadays, regulatory professionals are much more likely to focus on particular products, even within a product category such as medical devices—IVDs versus implants, for example. Additionally, there is more specialization in specific areas of the product lifecycle. With the apparent exponential evolution of technology, I foresee this granularity within the profession continuing.

Q   **How do you think the profession will change over the next five years?**

A   With a background primarily in the medical devices sector, I see a few areas, including software as a medical device, cybersecurity, artificial intelligence and personalized medicine as a result of genetic testing, that are having a major impact on how products are regulated. I anticipate that growth in these areas will be exponential and will present significant challenges at the overlap between scientific and technological innovation, and regulation. It will also present opportunities and challenges in the recruitment and training of regulatory professionals with the appropriate skill sets.

Q   **How would you characterize the relationship between regulators and regulated industry today, and how has it changed over time?**

A   Generally, the relationship between regulators and regulated industry has improved over the years. I believe the opportunity to build working relationships is encouraging and has gone a long way in collectively resolving or addressing meaningful solutions to challenging issues. Examples of these include FDA's Digital Health Software Precertification Program; FDA's building of the National Evaluation System for

Health Technology; Health Canada's Scientific Advisory Panel for Software as a Medical Device; and its Device Advice: Pre-Clinical Meetings pilot project. There continue to be opportunities for improvement in the "customer service" area, but I have noticed a concerted effort to address that as well.

Q   At what point in your career did you begin thinking of yourself as a regulatory professional?

A   I was fortunate during my career to have exposure at both the domestic and international level. This came relatively early on, and I think at this point it was obvious to me that working in regulatory was a defined career path whether you were working for a regulatory authority or part of the regulated industry.

Q   What are the qualities that make a good regulatory professional?

A   Knowledge of acts, regulations, guidance, directives, etc., and understanding the purpose of regulation are fundamental to good regulatory professionals and their role in providing safe, effective and high quality products to patients in a timely manner. Additionally, understanding the needs, challenges and responsibilities of each stakeholder—the 360-degree approach—in the delivery of healthcare is paramount. The ability to build and nurture trust and effective working relationships is also extremely important. RAPS' Regulatory Competency Framework does an admirable job in capturing many of the qualities that make a good regulatory professional.

Q   What has been the most rewarding thing about your career?

A   I have been fortunate and taken great pleasure throughout my career to engage with people and be involved in a community from all around the globe who are motivated and share a common set of principles and goals.

Q   What do you do outside of work that you are particularly proud of?

A   At this point in my career, I take pleasure in engaging with young people who seek advice and guidance as they contemplate their career interests and pathways. Their enthusiasm is reassuring and infectious and provides a certain motivation for me as I continue with my own career.

Q   What inspires you?

A   I continue to be inspired by and attracted to initiatives that take risks and embrace change, creativity and innovation to address problems or challenges. I hope I will always be motivated to explore how to accomplish something instead of languishing on the reasons why it supposedly can't be done.

This interview was conducted by Zachary Brousseau, RAPS senior manager, communications.

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Professional Development: Benefits of Obtaining Professional Qualifications

By Orin Chisholm, GCULT, PhD, SFHEA

This article discusses the benefits of formal qualifications for a regulatory career and highlights some of the English-language Master's-level courses offered globally.

Introduction

Many national governments today have policies in place to foster growth of the medical technology and biopharmaceutical industry to contribute to the new knowledge economy. As the industry grows, organizations continue to face increasing pressure to find and retain talented and suitably qualified staff across a range of functions involved in the discovery and development of new therapeutics. This is especially pertinent to the regulatory affairs function. The skills gap for suitably qualified staff can be addressed by graduate programs delivered by higher education providers.

Benefits of Education and Professional Development for Organizations

Increasingly organizations in the therapeutics industry are developing as "learning organizations" and as such they value creating, acquiring, interpreting, transferring and retaining knowledge, which leads to a competitive advantage for the organization.[1] As the learning organization evolves, higher education providers are increasingly partnering with industry to identify workforce needs and develop appropriate courses to meet these needs. As therapeutics become more complex, the clinical and regulatory environments become more complicated, pricing environments become more restrictive and demands from patients and healthcare providers for new therapeutics increase, universities can provide a unique environment where individuals with disparate backgrounds can come together to discuss new approaches to both the opportunities and risks facing the industry.

Organizations that measure the benefits of education, training and professional development of their staff find increases in productivity improvement, organizational performance, sales or revenue, and overall profitability accruing from such activities, particularly when external education is supported and aligned with the company performance management system.[2] In addition, the organization's support of training, education and development can have an impact on its reputation as a favourable place to work.

Lifelong learning is an important aspect to employees maintaining currency and competitiveness in the business environment affecting the pharmaceutical industry today.[3] A highly educated workforce is essential to being able to deliver agile, innovative thinking to develop new processes and frameworks around complex, novel therapeutic products coming through development.[4,5]

Skilled regulatory professionals are in short supply in some regions and companies can no longer rely on just on-the-job training to meet their needs for professional development of regulatory staff with the increasing body of knowledge required to work effectively in this field.[6, 7] Employers can create a supportive environment for staff wanting to pursue personal and career development by embedding a culture of learning in their workplace and encouraging staff to undertake further learning.[8]

The World Economic Forum suggests that the creation of relevant programs and courses developed in partnership with universities that have appropriately qualified teaching staff can facilitate the needs of industry for workforce reskilling.[9] Furthermore, the opportunity to learn in new and different ways and environments directly correlates to enthusiasm and inspiration of staff in the workplace. It improves staff morale, raises the bar for performance and pushes the organization to constantly improve.

Investing in professional development of employees helps them feel valued and that their employer is willing to help them reach their full potential. It also allows employees to be more aware of changing trends and directions in their industry.[10]

Benefits of Education and Professional Development for Individuals

As the industry grows, organizations continue to face increasing pressure to find and retain talented and suitably qualified staff. With tighter budgets and less time to develop in-house training resources, an optimum method companies can use for retaining talented staff is to provide access to external training by way of educational benefits such as paying for part of all of a relevant degree. With the emphasis on new ideas, futures thinking, research and development that occurs in universities and new approaches to educational pedagogy, they are in a unique place to deliver the cutting-edge training needed for staff involved in innovative approaches to therapeutic product development and regulation.

Training and development have a positive impact on the performance of individuals in an organization through acquisition of new knowledge and skills.[11] Declarative, procedural and strategic knowledge can all be enhanced by training. With an increase in PhD-qualified staff entering the industry, in-depth education and knowledge of the pharmaceutical industry and the regulatory function is required on top of the deep product and therapeutic area knowledge already obtained from postgraduate research degrees.[12] It is therefore beneficial for such incoming staff to undertake further formal education in regulatory affairs and pharmaceutical medicine. Graduate programs can be used to provide lifelong opportunities to support mid-career transitions. For example, staff wanting to transition into regulatory affairs from other internal functions such as clinical research, medical information or quality assurance.

Self-efficacy and self-management are enhanced as participants in academic programs learn to manage competing priorities of work, family and study. Cultural awareness can be enhanced by participating in formal education as participants need to interact with other students from varying backgrounds, who, as higher education becomes more global, are living in other countries. Indeed, many of these aspects are now emphasised in the learning outcomes (such as advanced disciplinary knowledge and skills and communication, adaptive and interactional skills) for academic programs.[13]

Different levels of competence are required at different levels of career progression in regulatory affairs and continual professional development can facilitate progression through these career levels.[14] For example, the RAPS Regulatory Competency Framework

and Guide[15] has a hierarchy of knowledge and understanding of scientific and health concepts at different career stages, including:

- Level I—understands scientific and health principles related to healthcare product development and regulations
- Level II—keeps abreast of and assesses the scientific and/or clinical advances that impact healthcare product development and regulation
- Level III—remains up-to-date on scientific and clinical advances that impact healthcare product development and assesses the relationship to regulation and regulatory issues
- Level IV—serves as a thought leader in the understanding and application of evolving basic and translational science, regulatory science and public health to develop new approaches to improve the development, review and oversight of healthcare products and identifies and proactively responds to scientific and/or clinical advances that impact healthcare product development and regulation

Different levels of formal courses in regulatory affairs can address these levels; for example, an introduction to regulatory affairs course that provides a basic understanding of the development process for new therapeutic products, how a product navigates through clinical trials and regulatory approvals and how it is funded might be suitable for the development of skills and knowledge for the early levels of a regulatory affairs career. Courses covering more advanced topics such as regulatory intelligence, international regulatory affairs, leadership in regulatory affairs and how regulatory staff can strategically influence the regulatory landscape to ensure it is fit for purpose as new challenges to regulatory decision-making arise may be of more benefit to staff in the higher levels of their career progression.

At an individual level, university education provides an opportunity for individuals to gain personal fulfilment, challenge themselves and develop the self-confidence to advance their career. It can be difficult in the day-to-day busyness of work to stop and take time to consider big picture issues, where an individual's role fits into the whole therapeutic product development process, how the future of regulatory science is evolving and what one may need to ensure skills and knowledge are up to the task to meet future career requirements. Taking time for formal study can provide this opportunity.

Obtaining a relevant higher degree can differentiate the individual in the marketplace and show potential and current employers one's commitment to the field of expertise and openness to new ideas. Furthermore, participation in formal education expands the individual's network, which can lead to future career opportunities, invitations to join consultative committees and develop regulatory expertise by participating in high-level discussions and negotiations with government and other stakeholders regarding regulatory policy direction, in one's own country and internationally.

Master's-Level Courses

There are many Master's-level coursework programs available through universities globally (**Table 1**). Some courses specifically cover just regulatory affairs and in other cases, there is a concentration of regulatory affairs subjects within the program. Some are offered fully online, others face-to-face or mostly online with residential periods as well. In addition, there are many other shorter programs, such as graduate certificates, available through both universities and private providers. University-level programs must comply with strict quality assurance requirements for their programs, undergo periodic academic reviews and meet relevant government standards for the courses they offer. This provides assurance of the quality of courses offered by universities, whether they are fully online, face-to-face or a hybrid of these forms or education. International students may be able to take a full degree program from their home country. The mixture of courses and the emphasis of the subjects within each Master's program are often determined by the expertise of the faculty teaching into the program. In some cases, potential students apply for recognition of prior learning to be counted toward their degree or they may be able to undertake individual subjects without committing to a full Master's degree. They also may be able to take subjects from other providers and have them credited toward their degree. Universities also may offer research degrees in regulatory science including Master by research, professional doctorates (e.g., DRSc, DrPH) or PhD studies. Potential students should review

programs on offer and determine their individual educational needs, often during discussions on professional development with their managers, before choosing the appropriate program for their needs.

Conclusion

There are many benefits to the individual and the organization from staff undertaking formal education, training and development in their field and many opportunities to increase the skills development of regulatory affairs personnel as therapeutic products increase in complexity.

Table 1. Selected Master's Programs in Regulatory Science and Pharmaceutical Medicine (English Language)

Region	University	Name of Degree	Offering Mode	Website
Asia-Pacific	UNSW Sydney, Australia	Master of Pharmaceutical Medicine	online	https://med.unsw.edu.au/pharmaceutical-medicine
	University of Queensland, Australia	Master of Pharmaceutical Industry Practice	F2F	https://future-students.uq.edu.au/study/program/Master-of-Pharmaceutical-Industry-Practice-5703
	University of Sydney, Australia	Master of Medicine (Pharmaceutical and Medical Device Development)	F2F, online	http://sydney.edu.au/courses/master-of-medicine-pharmaceutical-and-medical-device-development
Europe	King's College London, UK	Master of Science in Drug Development Science	F2F	https://www.kcl.ac.uk/study/postgraduate/taught-courses/drug-development-science-msc-pg-dip-pg-cert
	PME Institute, University of Duisburg-Essen, Germany	Master of Science in Pharmaceutical Medicine	F2F	http://www.pme-institute.com/index.php?id=112
	TOPRA/ validated by University of Hertfordshire, UK	Master of Science in Regulatory Affairs	F2F	https://www.topra.org/TOPRA/TOPRA_Member/mscra/MSc_Regulatory_Affairs.aspx
	Trinity College Dublin, Ireland	Master of Science in Pharmaceutical Medicine	F2F	https://www.tcd.ie/medicine/pharmacology-therapeutic/postgraduate/msc/
	University of Basel, Switzerland	Master of Science in Drug Sciences, Master of Advanced Studies in Medicines Development	F2F	https://www.unibas.ch/en/Studies/Degree-Programs/Degree-Programs/Drug-Sciences.html, http://web.ecpm.ch/master
	University of Claude Bernard Lyon, Eudipharm, France	Master of Science in Pharmaceutical Medicine	F2F	https://www.pharmatrain.eu/diploma-master.php?id=8
North America	ASU	Master of Science in Clinical Research Management (Regulatory Science)	online	https://asuonline.asu.edu/online-degree-programs/graduate/master-science-clinical-research-management-regulatory-science/
	George Washington University	Master of Science in Health Sciences in Regulatory Affairs	online	https://healthsciencesprograms.gwu.edu/program/the-george-washington-university-regulatory-affairs-master-master-of-science-in-health-sciences-1527569596782
	Johns Hopkins University	Master of Science in Regulatory Science	F2F, online	https://advanced.jhu.edu/academics/graduate-degree-programs/regulatory-science/

	Keck Graduate Institute	Master of Business and Science (Clinical and Regulatory Affairs)	F2F	https://www.kgi.edu/academics/henry-e-riggs-school-of-applied-life-sciences/academic-programs/master-of-business-and-science/concentrations/
	Long Island University	Master of Science in Drug Regulatory Affairs	F2F	http://www.liu.edu/Pharmacy/Academic-Programs/Graduate/MS-Drug-Regulatory-Affairs
	Massachusetts College of Pharmacy and Health Science	Master of Science in Regulatory Affairs and Health Policy	F2F, online	https://www.mcphs.edu/academics/school-of-pharmacy/regaff-pharmeco-healthpolicy/regulatory-affairs-and-health-policy-ms
	Northeastern University	Master of Science in Biotechnology (Regulatory Science concentration)	F2F, online	https://cos.northeastern.edu/biotech/academics/ms-biotechnology/concentrations/
	Northwestern University	Master of Science in Regulatory Compliance	F2F, online	https://sps.northwestern.edu/masters/regulatory-compliance/index.php#Regulatory%20Compliance%20Curriculum%20&%20Program%20Tracks
	Purdue University	Master of Science in Biotechnology Innovation and Regulatory Science	F2F, online	https://polytechnic.purdue.edu/degrees/ms-biotechnology-innovation-regulatory-science
	Rutgers, State University of New Jersey	Master of Business and Science (drug discovery and development)	F2F, online	https://mbs.rutgers.edu/program/drug-discovery-development-online
	San Diego State University	Master of Science in Regulatory Affairs	online	https://regsci.sdsu.edu/
	St. Could State University	Master of Science in Regulatory Affairs and Services	F2F, online	https://www.stcloudstate.edu/graduate/regulatory-affairs/default.aspx?utm_source=website&utm_medium=redirect
	St. John's University	Master of Science in Pharmacy Administration	F2F	https://www.stjohns.edu/academics/programs/pharmacy-administration-master-science
	Temple University	Master of Science in Regulatory Affairs and Quality Assurance	online	https://www.temple.edu/pharmacy_qara/
	University of Florida	Master of Science in Pharmaceutical Outcomes and Policy (Pharmaceutical Regulation speciality)	F2F, online	https://onlinepop.pharmacy.ufl.edu/programs/degrees-and-certificates/masters-degree/
	University of Maryland	Master of Science in Regulatory Science	online	https://www.pharmacy.umaryland.edu/academics/regulatoryscience/
	University of Pennsylvania	Master of Regulatory Affairs, Master of Regulatory Science	F2F	http://www.itmat.upenn.edu/mra.html, http://www.itmat.upenn.edu/msrs/
	University of Southern California	Master of Science in Regulatory Science, Management of Drug Development, Medical Product Quality, or Regulatory Management. Doctor of Regulatory Science (DRSc)	F2F, online	https://regulatory.usc.edu/programs/
	University of Washington	Master of Science in Biomedical Regulatory Affairs	F2F	https://www.regulatoryaffairs.uw.edu/

For other courses, also see the RAPS website under Publications and Resources; University Degrees and Certificates.

References
1. Boston Consulting Group. 2010. Creating People Advantage 2010: How Companies Can Adapt Their HR Practices for Volatile Times. The Boston Consulting Group, Boston, MA.
2. Aguinis H and Kraiger K. "Benefits of Training and Development for Individuals, Teams, Organizations and Society." *Ann Rev Psychol.* 2009:60;451-74.
3. Quendler E and Lamb M. "Learning as a Lifelong Process: Meeting the Challenges of the Changing Employability Landscape: Competences, Skills and Knowledge for Sustainable Development." *Int J Cont Eng Educat Life-Long Learn.* 2016:26(3);273-293.
4. Ketteridge S. "Why Professional Development is More Important Than Ever in Regulatory Affairs." *Regulatory Rapporteur. 2018:*14(9);30-32
5. Small N and Wilkinson J. "Using Professional Development to Attract and Retain Talent." *Regulatory Rapporteur*. 2018:14(10);28-29
6. Drago D, Shire S, Swanson C and Feagin J. "Answering the Call for Excellence in Regulatory Education." *Regulatory Focus*. May 2014. Regulatory Affairs Professionals Society.
7. Drago D, Shire S, and Ekmekci O. "Improving Regulatory Education: can we reconcile employers' expectations with academic offerings?" *Ther. Innov. Reg. Sci.* 2016:50;330–336.
8. Op cit 5.
9. World Economic Forum. 2017. Accelerating Workforce Reskilling for the Fourth Industrial Revolution: An Agenda for Leaders to Shape the Future of Education, Gender and Work. https://www.weforum.org/search?query=Accelerating+Workforce+Reskilling+for+the+Fourth+Industrial+Revolution+An+Agenda+for+Leaders+to+Shape+the+Future+of+Education%2C+G. Accessed 27 July 2019.
10. Crawford M. "Why Professional Development Matters to the Success of a Company." *The Business Journals.* 2016. https://www.bizjournals.com/bizjournals/how-to/growth-strategies/2016/09/professional-development-matters-success-company.html.
11. Op cit 2.
12. Theodosiou M, Rennard JP and Amir-Aslani A. "The Rise of the Professional Master's Degree: the Answer to the Post-doc/PhD Bubble." *Nature Biotech.* 2012:34(4);367-8
13. Chisholm O. "Curriculum Transformation: From Didactic to Vocational Programs in Pharmaceutical Medicine." *Frontiers Pharmacol. 2019.* https://www.frontiersin.org/articles/10.3389/fphar.2019.00278/full. Accessed 27 July 2019.
14. Kawiak K and Patel K. "Regulatory Career Progression." *Regulatory Focus.* July 2017. Regulatory Affairs Professionals Society.
15. RAPS. 2016. Regulatory Competency Framework and Guide. RAPS website. https://www.raps.org/careers/regulatory-competency-framework. Accessed 29 July 2019.

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Focus on: Jethro Ekuta

By Zachary Brousseau

Jethro Ekuta, DVM, PhD, RAC, FRAPS, was most recently senior vice president for regulatory, safety and standards at Horizon Therapeutics. He has more than 21 years of experience in pharmaceutical research and development, and has served in a number of leadership positions with Johnson & Johnson, Genzyme, Bristol-Myers Squibb, Pfizer and others. He also is an active RAPS volunteer leader, having served in roles including chair of the RAPS Fellows Selection Committee and as a member of the Regulatory Affairs Certification Board (RACB), as well as being an author for RAPS publications and a speaker at numerous RAPS events. He recently completed his term as president of the RAPS Affiliate Board, currently sits on the RAPS board of directors and is the board's incoming president-elect.

Jethro was kind enough to answer questions for the latest installment of the *Regulatory Focus* series, 'Focus on…,' where we talk with regulatory leaders, thinkers and influencers on topics such as regulatory leadership, advice for less experienced professionals and personal approaches to work and life. In this interview we discussed areas including the importance of being open minded, helping people reach their potential and why he is so passionate about regulatory affairs.

Following is an edited transcript of my interview with Jethro:

Q **How did you get started in the regulatory profession?**

A My interest in regulatory affairs can be traced back to my days as a veterinary medical student. From the first day I received instruction in pharmacology, I fell in love with this subject and became fascinated with the idea of helping to conduct research and develop treatments for the many diseases of humans and animals for which there was an unmet medical need. My passion for drug development led me to work for the National Institute for Pharmaceutical Research and Development in my native country,

Nigeria. I left Nigeria to enroll in the PhD program in pharmacology at the University of Mississippi. Upon graduation, I received the prestigious National Research Service Award from the National Heart, Lung and Blood Institute of the National Institutes of Health to undertake postdoctoral training in cardiovascular pharmacology and neuropharmacology at Meharry Medical College. This was followed by another prestigious fellowship for training clinical pharmacology reviewers for the US Food and Drug Administration (FDA). This was when I decided to join industry as a regulatory affairs professional. I looked at my passion, training and skills, and I wanted to do something that could tap into my broad-based training, and regulatory affairs was the logical choice.

Q **How has the regulatory profession changed most significantly since you started?**

A When I began my career in regulatory affairs, many people perceived the profession as merely a necessary evil or even a barrier to getting products to market. The scope of regulatory affairs was not well-defined, so anyone could identify as a regulatory professional if that person was familiar with a few regulations. Regulatory affairs was not seen as a strategic function but as simply a compliance function. We have come a very long way from those days. Today, many organizations have realized the strategic value that regulatory affairs can bring to an organization and view regulatory professionals as strategic business partners. Today, many regulatory professionals are better armed with business knowledge through earning an MBA degree or taking other business-related training to help them understand the business, which in turn helps them gain the respect of peers in sales and marketing. Furthermore, RAPS' development of Regulatory Affairs Certification (RAC) established appropriate criteria for evaluating professional competency. Finally, technology has evolved at such a rapid pace that today's regulatory affairs professional must be a life-long learner to keep up.

Q **What would you consider to be your personal philosophy of life and work?**

A My personal philosophy is to first define a purpose for living. This allows me to know what is important to me and what is not, which in turn allows me to prioritize work and non-work-related lists of things to do. My life's priorities are: first, spiritual; second, relationships with family, friends and co-workers; third, work; and last, anything else. I believe that if I do the first two well, I will be able to do the third and other things just as well. As a people manager at work, I believe that if I take good care of the people who have been entrusted to me, they will take care of the work entrusted to us by our employer. Taking care of my people means listening to them, respecting them, caring about what matters to them at work and outside work, creating a nurturing environment where they can thrive, removing obstacles from their path and supporting them to be the best they can possibly be in every area of their lives. I am a firm believer that every human being is endowed with the potential to do great things, and our role is to help others uncover their natural potential and support them to unleash this potential for the good of society.

Q **What advice would you give to a young professional just getting started in regulatory? What bad advice are they likely to hear?**

A My advice would be to be an avid learner. What makes the regulatory affairs profession exciting for me is the fact that there is always something new to learn, and there are always unexpected problems to solve. To be effective, one must be humble enough to admit that no one knows everything or has the answer to every problem. Seek out role models in the profession and learn from their mistakes and triumphs; you don't always have to re-invent the wheel. Build trusting relationships with your stakeholders internally and externally. Trust is borne out of persistent integrity. Know what you don't know, but make a commitment to seek out relevant information. Always have a solution-oriented approach to challenges. Finally, except for a situation where you are asked to do something unethical or illegal, saying 'no' to a stakeholder need should be rare for a regulatory professional. Many challenges that a regulatory professional

tackles are not black-and-white. When there are no clear-cut answers, the regulatory professional would do well to present a range of thoroughly researched options, with clear explanations of the pros and cons of each, to allow for a risk-based decision. Bad advice would be to stand your ground at all times. Life is complex and you should be open to new information, which could call for a change in position. To simply stand your ground even in the face of new evidence clearly to the contrary would not only damage your credibility, but also is likely result in failure to achieve a desired goal.

Q **What is a common mistake you have seen regulatory professionals make, and how can they avoid it?**

A The most common mistake I have found regulatory professionals make is to quote a regulation in a manner that presents it as black-and-white in situations where there may be a range of interpretations. FDA is careful to point out that its guidance documents represent the agency's "current thinking" on a given topic and are not binding. Regulatory professionals must be open to more than one interpretation of a guidance or regulation. Inflexibility is one reason some stakeholders view regulatory affairs as an obstacle to innovation. The focus of the regulatory professional ought to be to explore a range of options that may meet the requirements of a given regulation and consult with the regulator prior to implementing the option of choice.

Q **How can regulatory professionals develop their leadership skills?**

A The typical regulatory professional is likely to experience situations that call for leadership from very early on in his or her career. It may be dealing with a crisis, leading a major submission or negotiating a position with a health authority. It is imperative that the regulatory professional possess or develop critical leadership attributes to achieve personal and organizational success. Development of these skills could come from mentors and role models, personal experience, classroom or virtual training, case studies, books, periodicals, professional journals, etc. The regulatory professional would do well to have self-awareness of his or her leadership skills and actively seek to close any gaps.

Q **What personality traits do you look for in the people you hire?**

A At the very top of the list for me is an attitude of learning. Someone who recognizes that he or she does not know everything or have an answer to every question, is willing to learn from others, admits and is willing to correct mistakes and is adaptable and collaborative is a good candidate. Other indicators of success are: work- and non-work-related experiences, including successes and failures as well as lessons learned from each; attitude toward problem-solving—do you take ownership for solving a problem or blame others for not solving a problem?—and level of preparedness for the role for which a candidate is interviewing. A candidate should at the very least know the job description and be able to provide concrete examples of how he or she will be able to perform the role effectively or acquire relevant knowledge to bridge any gaps.

Q **What type of company culture is necessary for the regulatory function to really flourish?**

A A company should recognize the value that regulatory affairs brings and be willing to commit resources to build an effective regulatory affairs team. Regulatory professionals can help a company to stop a failed development program early, saving much-needed resources for other programs that are more likely to be successful. On the flipside, a good regulatory affairs professional could also help to accelerate the development of a good asset when the right strategy is researched and applied. These are just two examples, and companies would do well to recognize such value and invest in regulatory staff.

Q **What do you see as the greatest challenge facing the regulatory profession right now?**

A Although the specific challenges that regulatory professionals face vary, the phenomena that underpin such challenges have not changed over the years. Regulations change, leading to changes in regulatory guidelines; novel technologies evolve, leading to new regulatory pathways and regulations. Organizations look to regulatory professionals for more guidance and insight, so the regulatory professional must learn about new things quickly to successfully meet these demands. The lines that demarcate product groupings are increasingly being obliterated, requiring regulatory professionals to be more versatile in their knowledge of different product types. Increasing levels of globalization without concurrent regulatory harmonization also presents significant challenges.

Q **What would you be doing for a career if you were not in regulatory?**

A I cannot imagine doing anything other than regulatory affairs. I have enjoyed this profession a lot and it has been truly rewarding for me personally and professionally. Each time I have veered off course slightly, I have always gravitated back to regulatory affairs. I am honored and privileged to have a role now in which I can combine my passion for regulatory affairs with the related fields of pharmacovigilance and quality. After I finally retire from working in industry, I would like to return to FDA, write books on diverse subjects and continue to mentor and train the next generation of regulatory professionals.

*This interview was conducted by **Zachary Brousseau**, RAPS senior manager, communications.*

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eCTD Submission Management

By Ryan McNeely

An initial marketing application submission is a major undertaking that requires a large team, numerous tools and a litany of subprocesses to work together in harmony for a successful outcome. Leaving any of this to chance is likely to result in missed timelines and excessive crunch time. With thorough planning, careful execution and the ability to navigate unexpected challenges, the odds of success can be greatly improved. This high-level walkthrough will raise important considerations when planning an electronic Common Technical Document (eCTD) submission.

Planning, Timelines and Organization

Good planning begins with a good road map. Most often this is an eCTD content plan, but it also may include Gantt charts, shared calendars or other tracking software. Regardless of the tools employed, it is critical to set target dates for each milestone at the most granular level possible. This means every document intended for the final submission should be tracked from development, authoring, content approval, submission building, document publishing, through final reviews. These target dates should be realistic and chosen with enough buffer room to withstand the inevitable unexpected delays that occur. It is important to not overlook parts of the process or make assumptions. For example, the planning document may have included review cycles, but not a specific amount of time to make any changes stemming from that review or time to verify the changes. It is essential to make these milestone dates as visible as possible. Depending on what tools have been selected, incorporating notification emails and color coding to highlight tasks with imminent due dates could be beneficial.

Effort should be made to take advantage of asynchronous timelines when building milestones. For example, the nonclinical and Chemistry, Manufacturing and Control (CMC) documents may be completed before the clinical and summary documents. Where this is

the case, there is no reason to wait for the rest of the submission to be complete before beginning the review process. Reviewing and approving sections of the submission on a rolling basis as they are completed will help minimize the bottlenecking that often leads to crunch time at the end of a large submission. With certain modules already locked down, teams can focus all their attention on newly authored pieces and submission finalization. This compartmentalization is not limited to the module level either— if possible, it would be advantageous to finalize certain studies or subsections of modules as early as possible.

The review process also poses logistical questions. A thorough Quality Check (QC) of a submission the size of an initial marketing application is likely to generate a long list of issues that need addressing. Each of these issues represents its own sub-process of evaluating the issue that was raised, deciding on a path forward if it is critical enough to address, making any corrections needed and verifying those in the final submission build. Roles and responsibilities should be clearly defined so it is obvious who owns each of these steps. It may be beneficial to assign someone to triage issues so that one person has complete visibility over all the comments coming from each functional area. A centralized tracking system for issues is incredibly helpful in recording the steps and resolutions associated with each issue that is raised during QC. Often sponsors rely on individual QC spreadsheets provided to each reviewer. This can lead to disorganization and difficulty managing version control. When there are multiple reviewers working on several QC spreadsheets each, teams could end up managing dozens of spreadsheets.

If possible, use a single shared document or preferably a cloud hosted solution to record and track issues. This way, everyone can have access to the same information during QC efforts to avoid unnecessary or duplicate work.

Managing the Submission Team

Despite one's best efforts, all plans are subject to change once they are in motion. The planning document is a living document that will need to be updated and adjusted to account for the unexpected. It is important to establish who owns the document and who is responsible its maintenance. This process should be clearly defined, and if multiple tracking solutions are being used, any changes to one need to be propagated to the others. Communication plays a key role here as changes to the timing of one milestone will likely have ripple effects on subsequent steps and the people involved with those tasks. The clinical team may not see a big issue with pushing the finalization date of a Clinical Study Report (CSR) by a week, but that may delay the authors from writing the related summaries, which in turn pushes the document publishing back and compresses the final review timeline. Ripple down effects are not always visible to the entire team. To combat this, it is important to keep everyone engaged and actively involved throughout the entire process. Authors may think their job is done once the content is approved, but questions frequently come up that require their input during document publishing and submission finalization. Content owners should expect to be responsible for their portions through final submission and continuing into the agency response period.

Cross training can be valuable as well to get people thinking about their influence in the success of other functional areas. A successful submission involves resources from regulatory affairs, regulatory operations, medical writing, IT, marketing, senior management and other areas all of which have differing types and levels of expertise. The more each group understands about what other groups are doing the higher the likelihood of developing a positive cooperative working environment. Everyone involved should have a basic understanding of the document publishing process and eCTD concepts even if they are not directly responsible for building the final submission. This training is most valuable when done in the early in your process or as part of the project kick off.

Another important question to answer when evaluating a team's submission readiness is how much of the work will need to be outsourced. This will be dependent on the size and structure of the organization and its long-term goals. Use a content plan to assess the scope of the submission and evaluate the staff and budget to ensure the team is able to support the work.

It may be possible to grow the internal team to support all aspects of the initial filing, but if additional resources are not expected to be needed for subsequent filings, it may not be economical to do so. This is where the flexible staffing of a vendor can be an

advantage. If employing vendors, it is important to evaluate and select one as early in the planning process as possible. They should be involved in the creation of the timelines and confirmation of the project scope to ensure all parties are aware of the milestones and have a plan to meet them. There are logistical hurdles to consider as well. How will content between vendor and sponsor be transferred securely? Are there any version control or archive issues if working in different systems? How does working with a vendor change the final review plan? Have these discussions in the very beginning of the planning stage and factor the outcomes into the timelines.

Once the team is established and trained, the working dynamic should be documented. Responsibility Assignment Charts (RACI) and organization charts are useful tools to ensure everyone is aware of who and what they are accountable for. They also will help to reassess whether there are any bottlenecks or issues as the project progresses.

Technology and Specifications

There are numerous technical considerations to address that can make or break a submission. The most basic of these is ensuring there is a stable IT environment for the team to produce the submission. If the team has only produced smaller presubmission and general correspondence submissions, it is important to realize that initial applications can potentially reach dozens of gigabytes in size once all the documents and datasets are included. Very rarely do organizations properly stress test their environment to ensure that the desktop environment's performance and storage are up to the task of working with this data at a reasonable rate. What's needed is sufficient space to store working copies of the application and the ability to transfer files fast enough to not hold up the review team as new versions of the submission build become available.

Once a basic working environment is created, assess what software is needed to complete the submission. At a minimum, an eCTD publishing tool, viewing tool and validator to produce, review and validate the submission will be needed. These can be acquired as a suite of tools from a single vendor or can be evaluated and chosen individually. A robust document management system is also important to assist with version control, approvals and storage. Cloud hosted collaboration tools can help keep track of team communications, project status and planning documents. To meet agency requirements of maintaining a validated software environment, all these tools will need to be tested and documented. This process can be more time consuming than expected due to the number of people involved and the extensive documentation requirements.

Health Authority Changes

Once implemented, it will be important to maintain eCTD publishing, viewing and validation tools as agencies can issue new technical specifications and changes that could have an impact on the tools currently being used. These updates typically come with a mandatory implementation date, so be aware of those cut offs as timelines are being developed.

Guidance updates occurring mid-stream also can be a risk. Typically, agencies provide an adoption period before they go into effect, so the regulatory team needs to be aware of what is on the horizon. For example, FDA has issued a number of changes to their data standards and requirements over the past several years encouraging sponsors to move toward their preferred formats of SDTM, ADaM and SEND. These mandates were driven by study start dates, and sponsors that did not plan to collect and present their data in the required format would have been left scrambling to remediate. Guidance documents are frequently updated with clarifying language, changes to metadata and other critical information that could impact the submission. To ensure teams stay current, it is important to monitor agency websites, work with contacts at those agencies and read industry publications.

Submission of the Initial Application and Beyond

Once the submission is produced, develop a plan to submit it to the intended agency. Depending on the region, this may be through an online gateway, physical mail/media or in person delivery. Mature eCTD regions such as the US, Canada and EU employ online gateways which offer the most convenient means of submission; however, there is still

an initial setup hurdle to clear. Account creation, signature registration, test submission dispatch and any IT changes required in the system to support the gateway all take time and consideration to complete. It is also advisable to have more than one team member complete this process for redundancy. If submitting to a region where physical media must be delivered, plan for the logistics and additional time for a courier to deliver the media. In person delivery will required coordination with the agency to schedule an appointment.

So what's next after the team has successfully made it through the early stages and planned an initial filing, authored all the content, published and built the submission and submitted on time? Response periods differ depending on the Health Authority, but regardless of the agency, be prepared to respond to questions in a timely manner. This may be at a scheduled interval such as an EMA 120/180 day submission or on the ad hoc basis that US FDA and other agencies employ. Ad hoc questions often require rapid responses, so ensure the team is ready and able to receive the feedback, develop the necessary documentation and publish the related submission on very short timelines. These submissions can range from very brief Q&A to large compilations of additional data and studies.

Once the agency's requests have been satisfied during the initial response period, it will be time to plan for submissions relating to product approval. These will include correspondence with the agency, labeling materials and launch materials such as advertising and promotional submissions. Postmarketing requirement submissions, safety updates and other maintenance submissions continue from there. Simply put, the burden will be ongoing.

If the proper processes and planning have been established prior to the initial filing, the organization will be well prepared to meet these challenges. Unforeseen problems are inevitable in this type of work. The more thorough the plan for what to expect, the better positioned the organization will be to respond to the unexpected.

About the Author

Ryan McNeely is a regulatory operations manager at Accenture Life Sciences Solutions with nine years of experience producing INDs, NDAs, MAA, and other regulatory submissions. He can be contacted at ryan.p.mcneely@accenture.com.

Focus on: Minnie Baylor-Henry

By Zachary Brousseau

Minnie Baylor-Henry has served two separate stints as one of Johnson & Johnson's top executives, most recently as worldwide vice president for regulatory affairs for J&J's medical devices and diagnostics business, overseeing global regulatory strategy for numerous products. She also has been with Deloitte & Touche as a national director for regulatory and capital markets consulting, and with the US Food and Drug Administration (FDA) in roles including national health fraud coordinator and director of FDA's Division of Drug Marketing, Advertising and Communications. Today, Minnie is the president of her own consulting firm, B-Henry & Associates. She is active with several professional organizations, including RAPS, and has led several RAPS workshops for aspiring regulatory leaders.

Minnie graciously shared her thoughts on leadership, mentoring, diversity and more for Regulatory Focus' interview series, 'Focus on…,' where we talk with regulatory leaders, thinkers and influencers on such topics, as well as personal philosophy, inspiration and advice for new professionals.

Following is an edited transcript of our interview:

Q **How do you explain the role of the regulatory affairs professional to someone unfamiliar with the profession?**

A The regulatory affairs (RA) professional is part of a team charged with bringing pharmaceuticals, devices and consumer health products to market. RA plays a unique role since it is one of the only positions actively engaged from product inception through research and development, application submission, approval and postmarketing. The regulatory professional must thoroughly understand the laws, regulations, standards, directives and other requirements of a particular country or region where the product will be registered, and must ensure that everything the company is doing in support of bringing a product to market complies with the various requirements.

The RA professional assumes the role of liaison between the company and the health authority. Internally, RA is also a liaison between many of the other functions within the R&D team, as well as legal, finance, quality assurance, supply chain, medical, commercial, communications and government affairs.

Q **What is the most important skill for a regulatory professional to have or develop?**

A An effective regulatory professional must be an excellent communicator in both written and spoken communications. Since the RA professional spends a great deal of time either explaining regulations internally within the company or explaining the company's position to health authorities, effective communications skills are critical. This is not to minimize the importance of being able to understand the science and the intricacies of the regulatory requirements, but it goes without saying that such would be necessary. However, without the ability to convey this information, the vast amount of regulatory and scientific knowledge would not be well understood internally or externally.

Q **What are some of the most fulfilling experiences you have had during your regulatory career?**

A The opportunity that set me on the pathway to becoming a regulatory professional was at FDA. The agency was an exciting, intellectually challenging and professionally fulfilling place to work. I would highly recommend FDA for professionals trying to decide on a career direction. I remember thinking I'd stay at the agency for maybe three years, but I ended up staying for eight and a half years, and when I left, I did so for a new experience, and not because I had regretted my career choice. In fact, it was just the opposite. If someone is looking for a challenging environment where every day, you are learning something new, I would recommend you consider FDA. After my time at FDA, the opportunity to learn pharmaceutical, OTC and device regulatory affairs from an industry perspective was the right next step for me.

Q **What is the best career decision you ever made, and why?**

A This is easy: joining FDA. FDA launched my career in regulatory affairs.

Q **How would you describe your style as a manger and leader?**

A I think I am a servant leader. My main goal is to serve the team that I have the privilege to work with. I try to be a good listener and to be empathetic. I seek cooperation from my teams, but I can be persuaded to try a different pathway if it seems reasonable. I am very invested in growing new talent, and I am not afraid to work with untested professionals in order to build the next RA leader. While at J&J, we started a program to recruit recent graduates from masters of regulatory sciences programs. These new professionals rotated to different J&J companies for two years and, if successful, would be given opportunities within the company. Not all participants successfully completed the program, but all gained practical experience. The fact that I may have contributed to the launching of their careers in regulatory was the best reward.
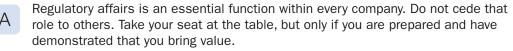
Q **Have you mentored someone? If so, what do you feel each of you learned from the experience?**

A Yes, I have mentored many professionals, some at J&J, Deloitte, Howard University, and outside of these organizations. Today, I continue to serve as a mentor to several professionals. During our conversations, there are the obvious problem-solving situations and opportunities to discuss different workplace scenarios. However, the most meaningful experiences have come from young professionals needing a boost of

confidence to help them embark on new opportunities when they may have been second-guessing whether they were truly qualified.

Most of my mentees have been women. Often, our discussions involve balancing career, family life and community involvement. As an African-American, female RA professional, I am keenly aware that there are just not very many senior level role models in the regulatory profession who are people of color. However, the profession is getting more diverse. I am quite pleased, but not completely satisfied, that our industry is recognizing and promoting RA professionals of color. So, what I have learned is, I have an obligation to give back. I take seriously the much-used expression that was famously paraphrased by President Kennedy, "For of those to whom much is given, much is required."

Q What advice do you give to aspiring regulatory leaders?

A Regulatory affairs is an essential function within every company. Do not cede that role to others. Take your seat at the table, but only if you are prepared and have demonstrated that you bring value.

Q What are the top two or three traits a regulatory leader needs to have?

A An effective regulatory leader must be a good listener, great communicator and effective team player. RA professionals are part of a larger team within government or a company. The successful leader will understand the importance of regulatory expertise to the overall success of the company, rather than selfishly viewing the role as an opportunity for individual stardom.
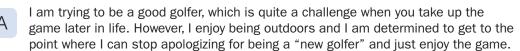
Q What commonly used buzzword or phrase do you purposely avoid using and why?

A My least favorite is "above my pay grade." For the regulatory function to be successful, it requires the entire team to be engaged. Everyone must be willing to contribute. It is easy enough to avoid taking on difficult assignments, but I have always appreciated the RA professional who is willing to attempt a difficult task or who methodically looks for answers to difficult questions. These intellectually curious professionals exercise good judgment and will ask for guidance when needed rather than punting to those at a higher "pay grade."

Q What inspires you?

A I am inspired by the opportunity to give back to my community, my profession and to others who may not be as fortunate as I have been. My husband and I frequently talk about how blessed we are to have had many great opportunities both personally and professionally. We must be generous in our willingness to give of our time and resources in order to help others.

Q What is something you are passionate about other than work or family?

A I am trying to be a good golfer, which is quite a challenge when you take up the game later in life. However, I enjoy being outdoors and I am determined to get to the point where I can stop apologizing for being a "new golfer" and just enjoy the game.

This interview was conducted by Zachary Brousseau, RAPS senior manager, communications.

Cite as: Brousseau Z. "Focus on: Minnie Baylor-Henry." *Regulatory Focus.* 28 March 2019. Regulatory Affairs Professionals Society.

How I Returned to Regulatory Affairs After a 10-Year Break

By Olivia McBride

The decision whether or not to take a career break can be an agonizing one. You might be thinking about stepping away to raise a family, care for an ailing relative, take a sabbatical, because of redundancy or for a number of other reasons. Whatever the reason, many consider it to be professional suicide.

It doesn't have to be. I was able to make a successful return to the world of regulatory affairs after a 10-year career break. That's not to say it's easy. There are many challenges you might face going back to work after a long absence, but there are steps you can take to regain your career. It may even be possible to negotiate terms that will help make it easier for you to be more successful when making your return.

Deciding to Take a Career Break

In 2004, I was a global regulatory affairs manager for a leading pharmaceutical company, 30 years old and an expectant mother. I had started my career as an associate regulatory manager and had worked my way up to project lead, managing a global team responsible for multiple, simultaneous Marketing Authorisation Application (MAA) submissions for the company's biggest product It was a very exciting and challenging role, and I absolutely loved it.

I took the UK's statutory maternity leave of 52 weeks, planning to return to work in August 2005. However, the three-hour commute would have meant putting my daughter into nursery for 10 hours a day, and I didn't want that. I took a deep breath and decided to resign to take an indefinite career break so I could stay at home and raise my family.

Ready to Return to Work

Fast forward to September 2014—10 years and three children later—my youngest son had started going to nursery a few mornings per week, and I felt it was time to think about a return to work.

Returning to work after such a long break is a daunting prospect. It may be difficult to think of yourself as a professional person, and it's easy to question yourself. Am I still employable? Has the industry moved on too much? Will I be able to do it again? How will I be seen by my peers? Are my skills out of date? Does the need for flexibility and a work-life balance make me less attractive to potential employers?

It's not an easy path to navigate and there are many challenges to overcome, but I can tell you from personal experience that it is possible.

The regulatory profession is dynamic and things are always changing. New regulations come into force, new procedures are introduced and changes in technology move quickly. But the regulatory world is a small one. Highly motivated, experienced managers with solid scientific backgrounds, communication and analytical skills, attention to detail and project management experience will always be sought after.

Getting Back up to Speed

During my 10-year break, I had not kept up with the regulatory environment or latest regulations. I had simply devoted myself wholeheartedly to being a full-time mum. So the first thing I had to do was get myself back up to speed.

A simple way of finding out what is happening in the biopharma and medtech industries is to sign up for relevant newsletters, such as RAPS' RF Today, and to read regulatory journals and publications, including Regulatory Focus. For the latest regulations in force and best practices, look on individual health authority websites to see what's new.

You will need to be able to "talk industry" in any interviews even if you're not technically an expert. So make sure you know about important regulations that may have been implemented since you left the field and understand their impact. For me, it was the Paediatric Regulation (2012), variations guideline (2008) and the revision to the Clinical Trial Directive (2014).

In addition, familiarize yourself with new legislation, regulatory procedures, timelines for procedures, content of applications, industry trends, the latest buzzwords and how technology and processes have evolved and what the practical implications are for doing your job.

Building Confidence

One of the biggest challenges you may face when returning to work is regaining confidence in your own skills and abilities. Don't underestimate what you can offer an employer based on your past experience and other transferrable skills. I remember thinking 'what kind of skills do I have now?' But when I really sat down and analyzed everything I had done and could do, it was clear that I had a lot to offer a potential employer.

Spend some time taking inventory of your skills, including those you may have gained since being away from full-time work, and where your strengths lie. Being a self-motivator and team player, organization skills, working well under pressure, good communication skills, adaptability and confidence are all attractive traits to a potential employer.

Write down any recent achievements even if they're not work-related. Have you been involved in active fundraising or done any other volunteer work? These experiences help show that you haven't been idle during your career break.

It can be helpful to talk with former coworkers or previous employers about projects you worked on together to refresh your memory of past achievements. Getting other peoples' perspectives on your strengths and significant contributions can give you a real confidence boost.

Consider taking a refresher course to boost your confidence. I did a proofreading course just to get my brain working in an analytical way again.

Get Your CV Ready

An up-to-date CV or resume is imperative. There are many resources and examples online regarding proper formatting, content and word choice. Make your CV concise and snappy. Use bullet points to emphasize your skills and experience. Make it stand out despite the gap.

Bringing my CV up to date was not difficult. I had hardly anything to add except my career break, some PTA fundraising activities and the proofreading course.

Networking

It is vital that you make yourself visible in a professional capacity and let the right people know that you are available for work again. Make sure your LinkedIn profile is up to date, and stay active on the site, connecting with colleagues and sharing relevant news and information.

Of course, LinkedIn isn't the only way to connect. I emailed some of my old colleagues and met up for informal chats. This was not only brilliant for boosting my confidence, it also gave me opportunities to ask questions, learn more about important trends, hear views on the current state of regulatory and how things have changed, and get potential job leads.

Most companies have a referral scheme in place to save money on recruitment costs. Networking with colleagues can be a great way to find out about potential career opportunities that may not be advertised or available through recruitment consultants.

Looking and Applying for Jobs

Upload your CV to online jobs sites, such as Total Jobs, Monster and Indeed. Be clear about the location and type of work you want or you may be inundated with irrelevant calls and emails from potential recruiters. On the other hand, don't make the criteria too limited and be careful not to dismiss everything that doesn't fit your criteria exactly. Some might still be good opportunities to pursue.

Your return to work gives you the opportunity to decide what kind of job you want and what your ideal terms would be. Be clear and honest with yourself about what you are looking for and what you can realistically commit to. By targeting the kind of job you want, you're more likely to find something that meets your needs rather than hoping to negotiate suitable terms. If flexible working is an important criteria for you as it was for me, you can identify favorable companies by examining at their HR policies.

At first it seemed like I would have no chance of finding the part-time, home-based regulatory work that I wanted. Most advertised positions I saw were full time, very few were home-based, and none seemed to offer any kind of school holiday flexibility. But I stuck to my guns, told recruiters what I wanted and kept looking.

Be Proactive

I was sent a full-time position by a recruiter that I almost dismissed as I was only looking for part-time work. However, on closer inspection, I learned the company was very open to employees working from home, so I decided to pursue it. I found out who the head of regulatory was and sent my CV by email, along with more about me, my experience and what I could give in terms of hours and time. This outreach led to a telephone interview and eventually a job offer.

Flexible jobs are rarely advertised. They are usually negotiated by someone already with the company or you have to go out and seek them for yourself. Smaller companies may be more flexible than larger ones for opportunity to hire the right person.

Preparing for Interviews

As with any job interview, you need to do your homework on the company and its products. Most interviews for regulatory affairs jobs take the form of a competency style interview. For these, you will be asked to give examples of a time when you have demonstrated a certain skill set, behavior or attitude. You will need to be able to describe a situation or problem you have encountered, what actions you took to solve it and what the outcome

was. The type of competencies you may be asked about can include communication, teamwork, analytical skills, leadership, independence and creativity.

To prepare for this type of interview, look at the type of competencies you think will be important for the role. The job description will usually include a list of skills and attitudes required. Use this list to come up with one or two examples from your prior work experience.

The two key things you'll have to convince a potential employer of, after an extended absence from work, are your commitment to work and your technical ability.

Be ready to talk about your career break. Start thinking about your time away in a positive light. Did it give you needed time to raise your family and pursue other interests? Are you now coming back to the workforce with renewed vigor, excited to embrace new opportunities? Think of how you've added to your skill set with other activities you've been involved with such as volunteer work or taking courses. Make it clear your career break does not indicate a lack of commitment. Discuss your break but don't apologize for it.

Regarding your technical and job skills, focus on your previous work experience, big projects you've worked on and the problems you were able to overcome in those. You will already have a list of all your skills, strengths and achievements. Review and be ready to discuss them.

Being able to start immediately without working a notice period also can be very attractive to an employer looking to fill a position quickly. This may give you an advantage over other potential candidates.

Don't be shy in asking about flexible working policies, company culture and expectations. It is better that you know early on, rather than later when your child is sick or you need to attend a school event.

Volunteering as Opportunity to Prove Your Value

Volunteering to do a short-term project or assignment is a great way to let potential employers know what you are capable of. For the job I accepted, I opted to do a number of sample assignments as a gesture of good will. This was not compulsory for the job offer, but gave my future employer confidence in my ability to read and interpret the current guidance and apply basic regulatory skills.

Back in the Game

Once you start your new job you'll likely find you have much to learn. There are new company systems and processes to become familiar with, finding your way around, learning who to contact for what and training to complete. It can be a bit overwhelming at first.

There is no substitute for on-the-job training in regulatory, and most of what you need to know you will pick up as you go along. Much of my getting back up to speed was done on the job. I read SOPs and sought out the latest guidance as I needed it for different projects. That's the beauty of regulatory affairs, as long as you know where to find the guidance and the latest regulatory frameworks, and have the medical or scientific background to read and interpret them, you don't need to know everything.

Whenever you start a new project or assignment, the first port of call is always the health authority websites for the latest guidance, templates and best practices. Also, look or ask for examples of recent work and, if possible, find a mentor to ask questions as they arise. Shared learnings are key to your success.

Managing Expectations and Working From Home

It's important is to be realistic about what you can achieve during your working hours. You cannot do a full-time job in part-time hours. Part-time work requires excellent time management skills. You will still have the same training requirements as your colleagues, as well as objectives to prepare and meetings to attend.

You have to be flexible. Often meetings or training courses are held outside your working hours and you will still be expected to attend. You need to be acutely aware of the deadlines and co-dependencies in projects, highlighting your progress and meeting deadlines to ensure continued progress. The key to making all this work is good

communication. Communicate with your manager and with project teams to manage expectations and ensure that both business needs and your family needs are being met.

I didn't go back to managing large-scale global projects because it would not have been achievable. However, I have been involved with some really interesting smaller-scale projects which are more suited to my part-time hours, but still offer challenges and professional development opportunities. This has included everything from mature brands licence maintenance (CMC variations and CCDS labelling updates) to pre-submission projects (writing a briefing document for scientific advice, SmPC development, writing clinical responses to Day 180 Centralised procedure EMA questions and writing preclinical and clinical eCTD modules). I love the variety of work, and I can work with shorter deadlines and achieve the satisfaction of completing important projects on a daily basis.

Working from home can feel a little bit isolating because you don't experience the same face-to-face interactions. Modern communications technology helps alleviate that to some degree, but you do need to be motivated, disciplined and dedicated to working from home to avoid getting distracted.

The rewards of returning to work, including renewed financial independence, job satisfaction, professional networking and being able to make use of my qualifications and experience, have been well worth the effort. I love being able to work and also be there for my family.

Summary

The regulatory environment is constantly changing and returning from a career break means you will have a lot to catch up on. However, it is relatively easy to get back up to speed on regulations and procedures. What doesn't change are the skills required to do the job. These don't disappear during a career break and you will likely have new skills and enthusiasm to offer a potential employer when you return.

A career break is not professional suicide. It's a wonderful opportunity to slow down and see what's really important in life and to return to work with renewed vigor, revitalized and excited about what you can contribute. It's also a chance to negotiate a work-life balance, with hours and flexible working arrangements, that fulfil both the company's needs and your personal needs.

About the Author
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Focus on: Bill Sietsema

By Zachary Brousseau

Bill Sietsema, PhD, has 35 years of experience in the pharmaceutical industry and is currently vice president of global regulatory affairs at Caladrius Biosciences. He has also held executive-level regulatory positions with Amgen, Kendle International/ INC Research and has taught pharmaceutical sciences at the University of Cincinnati, College of Pharmacy as an adjunct professor. He has authored 24 journal articles, four book chapters, 42 presentations and posters and is an inventor on six patents. He has published six books on regulatory topics, and served as editor of several RAPS publications, including Global Pharmaceutical and Biologics Regulatory Strategy and Risk Management Principles for Devices and Pharmaceuticals.

I recently interviewed Bill for the *Regulatory Focus* series, 'Focus on…,' where we talk with regulatory leaders, thinkers and influencers, sharing their thoughts on a range of topics. We also try to get to know these highly accomplished regulatory professionals better on a personal level and learn about what drives them. In our interview, Bill shared his thoughts on what it takes to be a good regulatory professional, the importance of ethics and what else he might see himself doing if he weren't in regulatory.

Following is an edited transcript of my interview with Bill:

Q **How did you first become involved in regulatory affairs and when did you begin thinking of yourself as a regulatory professional?**

A I had been working in clinical operations and sort of outgrew it. Since I was one of the few employees with a scientific background and with experience in strategy development, my employer provided me with an opportunity to work on some of the regulatory and clinical strategy aspects of the business. I was good at it, and it grew from there. Eventually I was asked to build a department to work with customers on their

regulatory needs and we called it Regulatory Consulting and Submissions. Once I had the word "regulatory" in my title, I thought of myself as a regulatory professional.

Q **What are the qualities that make a good regulatory professional?**

A I think a regulatory professional needs to have quite a number of skills and qualities. Ability to listen carefully and grasp complex issues is important. Ability to think creatively and find solutions is also important. But a regulatory professional also needs to know where to find regulations and understand them, and recognize where there might be room for negotiation and where there's not room for negotiation. A successful regulatory professional also needs to be able to explain regulations, strategy and science to others in the organization and frequently has to "sell" the best solution to others. Integrity is also critical—a regulatory professional needs to be able to tell the bosses when they are about to cross the line and step into something which is illegal or unethical.

Q **What advice would you give to a young professional just getting started in regulatory?**

A I would say young professionals need to identify one or more mentors who have been successful in regulatory affairs and have many years of experience. In a good mentoring relationship, the mentee benefits from the mentor's experience and the mentor benefits from the mentee's frequently more specific knowledge, creativity and quest to find the best solution.

Q **What do you see as the greatest challenge facing the regulatory profession right now?**

A The fact that regulations evolve and change on an ongoing basis is a huge challenge. Even the most experienced regulatory professional can't know it all and has to look up regulations and guidelines to make sure proposed strategy is consistent with current expectations.

Q **What impact has new technology had on your daily work or on that of your team within the last five years?**

A I'll go back more than five years on this, but in the old days the internet didn't exist and publications such as the Code of Federal Regulations came out on paper, making it challenging to find things. The ability to locate information on the internet and even just to search terms within a document has made us not only more efficient but able to gather more and better intelligence than previously possible.

Q **How do you think the profession will change over the next five years?**

A Until a few years ago, there was no formal educational curriculum in regulatory affairs. Everything had to be learned "on the job" or by experiences shared with other regulatory professionals. There are now university programs that train individuals for careers in regulatory affairs. This is a great boon to the profession as students can now train at the university before taking on a regulatory career. Students coming out of these programs have a head start compared to those that are learning on the job. The university programs have also helped to advertise the profession for students entering the industry.

Q **What makes regulatory a fulfilling/rewarding field to be in?**

A It's always changing. There is never a dull moment. And most problems have multiple solutions, so we get to identify possible solutions and then examine them

to see which one is the best fit for the particular problem at hand. I enjoy the detective work and strategy development that are such an important part of the job.

Q Do your personal values influence your decisions at work? If so, how?

A Yes, one of my personal values is to keep commitments that I make. It has served me well and influences how I prioritize my daily work.

Q What personality traits do you look for in the people you hire?

A I look for high energy, and also for the ability to think creatively without being constrained by feasibility. Feasibility can be assessed later but shouldn't prevent one from thinking creatively. Ability to collaborate is also important. Being successful in regulatory affairs means being able to work with colleagues in clinical development, manufacturing, medical affairs, quality, etc. All these functions have a stake in finding a solution, and in the outcome.

Q Do you have a habit—in work or life—that you think is unique or especially helpful to you?

A Yes, I am an early riser. I get up about 5:30 am and get the coffee maker going. I usually get a few hours of quiet time to work on particularly difficult challenges or on projects that require intense focus. Another benefit is that it gives more overlapping work hours with my colleagues on the East Coast.

Q What would you be doing for a career if you were not in regulatory?

A I love science and I love solving problems. I might have had a good career in forensic medicine.

Q What is something you are passionate about other than work or family?

A I love bicycling and will often bike 40 or more miles in a weekend. I have four bicycles, which really isn't enough, but I run out of space to store them. I also like to do home remodeling projects.

This interview was conducted by Zachary Brousseau, RAPS senior manager, communications.

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Making the Switch to Advertising and Promotion: My First 90 Days

By Steve Jwanouskos

After more than three decades of working directly with the development, approval or clearance and subsequent commercialization of medical technologies, I made the switch to advertising and promotion regulatory review. For anyone considering a similar move, I have some advice: Go for it!

Making the transition to any new job—regulatory or otherwise—can be challenging, but I found I was able to make the move more smoothly and effectively by following some simple steps in my first 90 days on the job. I found this idea and other helpful advice for developing and honing the job transition in a well-organized book titled, The First 90 Days, by Michael D. Watkins, from which I adapted the title for this article. What follows is based on my own personal experience. The opinions offered herein are my own and do not reflect those of my employer or any other third party.

First, before doing anything, I focused on just observing. During those first 90 days, I got to work every day at 7:30 am and stayed until 5:30 pm. I Tried to work at peak efficiency all day from prioritized to-do lists, always keeping in mind what I needed to do next. One of the most important things I did was to cultivate as many work connections as possible.

The Candy Jar

To help cultivate connections, I put out a candy jar and spent freely to fill it up with the really good stuff. To do this, I used my own money. I viewed it as an investment in my future, and the future means the 90 days that follow those first 90 days, and the 90 days after that and so on. After about a week, I put a sign on the candy jar, "You can have all the candy you want, but you have to introduce yourself." Most, if not all of my new colleagues took advantage of the free candy and the opening for an introduction.

The purpose of the candy jar was not to become the most popular person in the organization, but to learn about those who are the more successful, who stand out for

their institutional knowledge and their positive demeanor, those who work well cross-functionally and, therefore, know who's who. In the first 90 days, I aimed to accelerate my learning by associating with those who would be able to teach me what I needed to know and those who could help reveal what I did not know, which is impossible to learn on one's own. I knew that then, and only then, would I be nearing the time when I would begin earning my paycheck by contributing to the organization in a meaningful way.

Seek Advice and Knowledge

I also sought valuable advice from professionals who have excelled in the field of advertising and promotion for a long time. One such colleague, Linda Pollitz, a senior director of regulatory affairs, advertising and promotional labeling, provided me with a valuable reading list of guidance documents listed at the end of this article. To those sources, I would add a new guidance document that was just published in June 2018, entitled Guidance for Industry: Consistent with the Labeling. Each of these guidance documents are a must-read, especially for rookies in advertising and promotion like me. The quest for new knowledge is an important step and a major theme of this article.

The Importance of Integrity

It is critical to approach the first 90 days with integrity. I wanted to immediately establish my integrity as an essential element of my work and reputation. I found a great definition of integrity in the reminder the US Marines have at their departure point, Parris Island, SC. There, Marines are reminded before they deploy into harm's way to, in descending order of importance to:

- Tell the truth.
- Do the "difficult right," not the "easy wrong."
- Think of the group before yourself.
- Do not whine or make excuses.
- Only judge others on actions, nothing more.
- No matter how trivial the task, do your best at it.

In my opinion, following these standards in the first 90 days and beyond is vital—whether in the Marines, medical products advertising and promotion or any other field.

The Art and Science

For the specific skills to develop early during a transition to advertising and promotion, I asked the advice of an industry expert, Stella Li, department head, Advertising and Promotion Regulatory, Johnson & Johnson Vision. My first question was about what to expect as the biggest difference from my previous regulatory background, and how to adapt to it to be successful. Her advice was to recognize that review of advertising and promotions is "a work of art." She pointed out that the same message can be stated in a variety of ways, sometimes with just a subtle change in the nuance of an expression or a phrase. Consistency is the best one can strive for in this field, because there can be so many "shades of gray." Most standard operating procedures (SOPs) are not exhaustive (nor should they be) to be so prescriptive that there will be guidelines to follow. However, FDA guidances are very helpful for developing a consistent basis upon which to provide reliable reviews.

Other skills Stella identified as key to success were paying attention to detail and the ability to articulate the foundations of any given position. Being able to articulate not only my point of view, but also that of colleagues in other, related areas like marketing, helps me to gain a broader negotiating perspective, and minimize confusion, which John E. Abele, co-founder of Boston Scientific Corporation, once told me was the "arch-enemy."

To achieve success in regulating advertising and promotional claims, Stella advised that being able to work cross-functionally is paramount to "reaching compliance alignment while allowing effective messaging." Customers—both healthcare professionals and patients—are the at center of creating effective messaging, which is why everyone in senior management, advertising and promotion and marketing, among others, should

care about what is being said and how. Intrinsic in the pursuit of compliant and effective messaging will be disagreement. Disagreement should be recognized as part of a process to resolve things, and one should not take it personally.

During my first 90 days, I started by observing, learning and "devouring" seemingly endless SOPs. I don't think memorizing SOPs word-for-word is necessary, or even advisable. Instead, I would make it a point to have a copy of the released procedure where I was able consult it frequently. I would recommend getting to know the two top SOPs backward and forward, especially during those first 90 days.

Observe, Orient, Decide, act

It also is important to have an early "sit-down" with one's boss to discuss top priorities, both short- and long-term, to see how and where they fit with those of the organization. Putting everything into context ("orientation") is the next step after observing. I followed a process of observing, orienting, deciding and acting, a four-step sequence attributed to US Air Force Colonel John Boyd, and covered well in Robert Coram's book, The Fighter Pilot Who Changed the Art of War.

To summarize the idea, observe in a detached, objective manner searching for substance over style while looking for actions, not necessarily words, even if advertising and promotion involves primarily words. It is possible to orient by putting the flood of new information into meaningful context, so patterns and tendencies can be identified. Allow your perspective to be grounded in science. Your decision, supported by as much fact and data as possible, should be brought forward to the team as one option. Offer support regarding why you think this is the best option by using examples and appropriate details, possibly also demonstrating the weaknesses of other, less favorable approaches. Finally, act with clear purpose in executing a plan that includes the next step. Act decisively, without the dreaded "unforced error" fear that often plagues tennis players. Do not be the center of a spectacle, major or minor. I strived to apply these methods during my first 90 days and then continuously thereafter. The faster these four methods—observe, orient, decide, act—are accelerated, the easier the job becomes.

Conclusion

At the end of my first 90 days, I was looking forward to my next 90 days, when my focus would shift from making the job transition to delivering for the organization. Advertising and promotion is a fascinating, important role for a regulatory professional as one will likely be exposed to the newest ideas—some permissible and some requiring a little revision and assistance. In this role, it's possible to become recognized as a leader in the organization, which certainly is a nice extra perk. But it is important to always remember that authority and responsibility travel together. You can delegate your authority, but not your responsibility.

Recommended Reading

1. Coram R. Boyd. The Fighter Pilot Who Changed the Art of War (Biography). 2002. Little, Brown. New York, NY. ISBN 978-0-31679-688-0.
2. Watkins MD. The First 90 Days. Proven Strategies for Getting up to Speed Faster and Smarter. 2013. Harvard University Press. Boston, MA. ISBN 978-1-4221-8861-3.
3. Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs Guidance for Industry (April 2015). [Author's Note: guidance is primarily intended for pharmaceuticals, but premises asserted by FDA also may be applicable to medical devices].
4. Memorandum: Center for Drug Evaluation and Research, Food and Drug Administration, January 2017. Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products.
5. Medical Product Communications That are Consistent With the FDA-Required Labeling—Questions and Answers. January 2017. [Author's Note: superseded by number six].
6. Medical Product Communications That are Consistent With the FDA-Required Labeling—Questions and Answers. June 2018. Drug and Device Manufacturer.
7. Communications with Payors, Formulary Committees and Similar Entities—Questions and Answers. January 2017.
8. Guidance for Industry: Providing Regulatory Submissions in Electronic and non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs Guidance for Industry. April 2015.
9. Guidance for Industry: Internet and Social Media Platforms-Correcting Independent Third-Party Misinformation About Prescription Drugs. June 2014.
10. Guidance for Industry: Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices. June 2014.

11. *Guidance for Industry: Distributing Scientific and Medical Publications on Risk Information for Approved Prescription Drugs and Biological Products—Recommended Practices*. June 2014.
12. *Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics.* January 2014.
13. *Guidance for Industry Direct-to-Consumer Television Advertisements—FDAAA DTC Television ad pre-Dissemination Review Program.* March 2012.
14. *Guidance for Industry: Responding to Unsolicited Requests for off-Label Information About Prescription Drugs and Medical Devices.* December 2011.
15. *Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics.* January 2014.
16. *Draft Guidance for Industry and Food and Drug Administration Staff: Mobile Medical Applications.* July 2011.
17. *Guidance for Industry Patient-Reported Outcome Measures: use in Medical Product Development to Support Labeling Claims.* December 2009.
18. *Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved new Uses of Approved Drugs and Approved or Cleared Medical Devices.* January 2009.
19. *Guidance for Industry Patient-Reported Outcome Measures: use in Medical Product Development to Support Labeling Claims*. December 2009.
20. *Guidance for Industry: Help-Seeking and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms.* January 2004.
21. *Guidance for Industry: Industry-Supported Scientific and Educational Activities.* November 1997.
22. *Guidance for Industry: Promoting Medical Products in a Changing Healthcare Environment.* Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMs). December 1997.
23. *Food and Drug Administration Modernization Act (FDAMA)* 1997. Sec. 114. Healthcare Economic Information.

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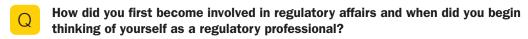
Focus on: Allison Komiyama

By Zachary Brousseau

Allison Komiyama, PhD, RAC, began her regulatory career at the US Food and Drug Administration (FDA) as a biologist and reviewer, and served as lead reviewer and consult on 510(k) premarket notifications, investigational device exemption (IDE) applications and premarket approval (PMA) submissions. Her specialty was in biocompatibility requirements for implanted devices. After FDA, Allison worked on the industry side in senior regulatory roles before starting her own consulting firm, AcKnowledge Regulatory Strategies. She holds the Regulatory Affairs Certification, and has served as a content expert for RAPS.

Allison shared her thoughts on new technology, the importance of people skills, how regulatory affairs is like rowing and more for *Regulatory Focus'* interview series, 'Focus on…,' where we talk with regulatory leaders, thinkers and influencers about their work, experiences, personal philosophies and advice for new professionals, among other topics.

Following is an edited transcript of our interview:

Q **How did you first become involved in regulatory affairs and when did you begin thinking of yourself as a regulatory professional?**

A After earning my undergraduate degree in molecular and cell biology, I continued down the academic path to graduate school where I studied neuroscience. Around my third year of grad school, I realized that while I really liked the bench (and my research), I felt both disconnected from people and too far removed from medicine. This was unfortunate, as those connections were why I'd originally chosen to do my PhD. I realized that I really wanted to be closer to medicine and helping people in a specific way: in other words, I wanted to move away from 'benchside' and closer to 'bedside,' without having to earn another degree. While in grad school, I was interested in regulatory science, and so I took a class about the history of FDA and how the agency regulates drugs, biologics and devices. I was hooked.

In 2009, I finished my PhD and moved to Washington, DC, landing a reviewer position in the Office of Device Evaluation (now known as the Office of Product Evaluation and Quality). It was during my time at FDA that I truly began to think of myself as a "regulatory professional." I loved the diversity of devices that I reviewed at the agency, as well as my colleagues. Every day was different and every device raised unique and interesting questions. My role at FDA truly merged my affinity for science with my love for medical technology.

Q **What makes regulatory a fulfilling/rewarding field to be in?**

A There are many fulfilling facets to this career; however, I would have to say my favorite is helping cool medical technology get to the patients whose lives it will improve. I've had numerous instances now where previous clients have emailed me with a story of how their device helped improve—and in a few cases saved—someone's life. That is such an amazing, rewarding feeling.

Q **What advice would you give to a young professional just getting started in regulatory?**

A I always advise that young professionals build and foster their network. I have found that most people in regulatory affairs are eager to support fellow regulatory professionals, and are quite generous with their time. Many of the colleagues in my network—many of whom I've met through RAPS, the San Diego Regulatory Affairs Network (SDRAN) or at conferences—have been integral to my success. Not only is your regulatory community valuable when you have questions, but they are also a great source of new clients and career leads.

Q **What impact has new technology had on your daily work or on that of your team within the last five years?**

A New technology has directly impacted the types of devices that we work on and submit to FDA. Many medical devices now incorporate mobile applications or some form of wireless technology that is used to share data with a healthcare professional. Other devices are now purely "software as a medical device" (SaMD), and use complex algorithms or artificial intelligence to help diagnose or treat a disease. Advances in technology have resulted in some regulatory growing pains as FDA strives to keep up with industry and understand the associated risks and benefits. Ultimately, I believe that these new technologies, along with our adoption of smartphones and tablets, have and will continue to improve healthcare. Over the last five years, I've worked with companies whose devices provide earlier diagnosis of life-threatening diseases, decrease healthcare costs by reducing the number of times a patient needs to travel to the hospital, and increase patient compliance to their treatment plans by means of a reward or reminder system. I find so much of the new technology inspiring, and it is exciting to be part of this fast-paced, growing device sector. I can't wait to see what the next five years will bring.

Q **How important is it to have good people skills to work in regulatory?**

A I firmly believe that having good people skills is essential to work in regulatory, although I have met a few in this field who seem to be successful without them. I have heard clients call my company their regulatory "translator," "therapist" or "sherpa," in addition to being their consultant. I believe it's valuable to read and relate to your clients and help them navigate their specific regulations and FDA feedback. You definitely have to be prepared to communicate with lots of different folks who possess a range of personalities. Connecting with people is one of the most enjoyable aspects of this work, and something I didn't get much of when running Western Blots at 2 am in grad school!

Q How important is it for regulatory professionals to be strategic thinkers?

A Being a strategic thinker is one quality you cannot do without in this field. This might seem like a career where you simply memorize the regulations, standards and guidance documents in order to establish the correct path forward. However, I've never known there to be a single, crystal-clear regulatory path for a medical device, with zero risks and 100% certainty. Evaluating and taking into consideration a client's pain points (e.g., are they short on time or money?), recent shifts in scientific premise (e.g., are there new biocompatibility concerns about a material that was previously thought to be safe?), and/or various updates to the regulatory landscape (e.g., how will FDA's new guidance on least burdensome provisions impact the content of an upcoming submission?) can dramatically increase the likelihood of success when it comes to the overall regulatory strategy for a device. Strategic thinking is a skill that is learned and honed over time, and increasing one's experience, reviewing case studies and working in a team all help to build this skill.

Q What other qualities are most important to be a good regulatory professional?

A Patience, determination, compassion, tenacity and fearlessness, just to name a few.

Q As a consultant, what types of clients do you most enjoy working with?

A Honestly, I love the clients who walk into an FDA meeting with an open mind and don't see the agency as "an evil entity that's trying to stifle our innovation." I am also thrilled when a client walks away from an interaction with FDA and says to me "wow, that was really great and way more collaborative than I thought it would be." In that moment, I feel as though everyone (my client, the reviewers and future patients) is a winner. As someone who used to work at FDA and who now represents medical device companies, I try to remind my clients that (similar to their own companies) the agency is made up of diverse, intelligent people who are passionate about improving the health and well-being of patients. I love when a client can appreciate that the responsibility to "protect and promote" public health shouldn't fall on FDA's shoulders alone, as that should be at the heart of industry's mission as well. If we can honestly communicate that we're all on the same page when we go into that meeting and that we all want what's best for patients, ultimately, we all benefit.

Q What do you do when you feel stressed?

A I am an avid rower, and have been since I was in high school. While the 4 am alarm clock can be brutal, I always find myself really calm and relaxed while out on the water with my crew at ZLAC Rowing Club. Being in the habit of getting up early also makes the occasional 5 am phone calls with international clients easier to handle (on those mornings I get an extra hour of sleep!) Rowing is the ultimate team sport, and similar to regulatory affairs in that everyone has to work together and be in sync to successfully make it across the finish line.
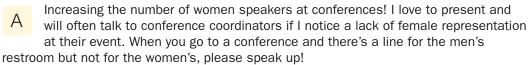
Q What commonly used buzzword or phrase do you purposely avoid using and why?

A While I use the phrase "it depends" on occasion, I use it sparingly and only if I can follow the statement with a sufficient explanation. "It depends" is often not a helpful answer, especially when you're a medical device company or an investment group looking for solid advice. I also find that some people use the phrase "it depends" when what they really mean to say is "I don't know." If someone truly doesn't know the answer, they should be comfortable with admitting that. The success of a regulatory strategy hinges on many factors, for example, the device design, changes in regulations,

or the results of bench testing. Companies want and deserve guidance on how these factors may impact them in the short- and long-term. Without reliable advice that they can use, well, maybe they're better off just hiring a fortune teller.

Q **What is something you are passionate about other than work or family?**

A Increasing the number of women speakers at conferences! I love to present and will often talk to conference coordinators if I notice a lack of female representation at their event. When you go to a conference and there's a line for the men's restroom but not for the women's, please speak up!

This interview was conducted by Zachary Brousseau, RAPS senior manager, communications.

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Curiosity
One of Life's Most Valuable Commodities

By Max Sherman

This article discusses the value in human curiosity for learning, living a more meaningful life and as an important tool for professional success. The author reviews several books on curiosity that outline why we are curious, explains different types of curiosity and suggests how we might not lose our curiosity as we age.

Introduction

While working for a medical device company, I frequently had the opportunity to interview new job candidates. One question I asked was about the books the prospective new hire has read or is reading. Reading habits are one indication of how inquisitive an individual is and speaks to their dedication to continued learning. An inquisitive person is more apt to be hired.

According to the literature, people with strong curiosity traits are generally more creative and better problem solvers. A growing body of evidence suggests that inquisitive people are more qualified to fill complex jobs and learn new skills faster. Moreover, the more curious we are about a topic, the easier it is to learn about it. A recent article, "From Curious to Competent," in the *Harvard Business Review*, noted that curiosity, defined as a penchant for seeking new experiences, knowledge and feedback and an openness to change is, perhaps, the most important of all job qualifications.[1] While the definition appears to be complete, scientists think differently about curiosity and have been investigating the effects of curiosity since the 19th century.[2] Over time, the working definition has included "a drive state for information." However, the scientific definition for what constitutes curiosity is still under debate.

New research indicates inquisitive people provide a wide range of benefits to employers. For example, curious employees are likely to make fewer decision-making errors. They also are less apt to employ confirmation bias (looking for information that

supports their belief rather than for evidence suggesting they are wrong) or to stereotype people (making broad judgments). Curious people view tough situations more creatively. Studies have found that curiosity is associated with fewer defensive reactions to stress and less aggressive reactions to provocation. Overall, natural curiosity is associated with better job performance. Inquisitive employees make more constructive suggestions for implementing solutions to creatively solve problems occurring in the workplace.[3] Thus, it behooves companies to cultivate employee curiosity at all levels and to treasure inquisitive minds. When triggered by design, employees think more deeply and rationally.

Curiosity for Learning

As mentioned above, the more curious we are about a topic, the easier it is to learn information about that topic. This finding has far-reaching implications, revealing insight into how curiosity affects memory and enhances learning, both in the classroom and the workplace. When curiosity is stimulated, there is increased activity in the brain circuit related to reward, a circuit that relies on dopamine, a chemical messenger relaying messages among neurons. Interactions between the reward system and the hippocampus put the brain into a state in which the individual is more likely to learn and retain information.[4]

Curiosity in Life

Curiosity also may be part of having a more fulfilling life. According to a recent book, "Curious? Discover the Missing Ingredient to a Fulfilling Life," by Todd Kasdan, curiosity is the "central ingredient" for living a more fulfilling life.[5] Kasdan claims curiosity is nothing more than what we feel when struck by something novel. It draws our attention to interesting things and plays a critical role in the pursuit of a meaningful life. Curiosity is about how we relate to our thoughts and feelings; it is not about whether we pay attention, but about *how* we pay attention to what is happening in the present. Only in the present can we be liberated to do whatever we want to do; it is a "razor-thin" moment when we are truly free. When we are curious, we exploit these moments by "being there," sensitive to what is happening, regardless of how it diverges from what it looked like before and what we expect it to be in the future. There is a strong correlation between curiosity and "mindfulness."

Types of Curiosity

There are several "types" of curiosity. "Perceptual curiosity" is engendered by extreme outliers, by novel, ambiguous or puzzling stimuli and it motivates visual inspection. Perceptual curiosity generally diminishes with continued exposure. The opposite of perceptional curiosity is "epistemic curiosity," which is the veritable desire for knowledge (the "appetite for knowledge" in the words of philosopher Immanuel Kant).[6] Curiosity has been the main driver of all basic scientific research and of philosophical inquiry, and it was the likely force propelling early spiritual quests. The seventeenth-century philosopher Thomas Hobbes dubbed curiosity the "lust of the mind," adding that "by a perseverance of delight in the continual and indefatigable generation of knowledge" it exceeds "the short vehemence of any carnal pleasure" in that indulging in it only leaves you wanting more.[7]

"Specific curiosity" reflects the desire for a particular piece of information. It attempts one to solve a crossword puzzle or to remember the name of the movie you saw last week. Specific curiosity can drive investigators to examine distinct problems in order to understand them better and identify potential solutions. Finally, "diversive curiosity" refers both to the restless desire to explore and to seeking novel stimulation to avoid boredom. Today, this type of curiosity might manifest in the constant checking for new text messages or emails or in impatience while waiting for a new smartphone model. Sometimes, diversive curiosity can lead to specific curiosity in that the novelty-seeking behavior may fuel a specific interest.[8]

Cultivating Curiosity

Most children are naturally curious, even to the point of endangering themselves. Curiosity is unique to human beings, begins almost at birth, but is frequently lost as we grow older. According to Ian Leslie in his book, "Curiosity," the challenge to not losing one's curiosity is to find new ways to make us continually hungry to learn, question and create.[9] One way is

to pique a person's interest in some topic. Parents are presented with the opportunity many times each day. Once curiosity is stimulated, there is increased activity in the brain circuits related to reward, which enables the brain to enhance learning and retain information.

Teaching Employees to be Curious

If your company wishes to include "curiosity" as part of training, "Edutopia," an educational website, suggests a number of ways to stimulate an employee's inquisitiveness, including:

1. value and reward curiosity
2. teach them how to ask quality questions
3. teach skepticism by asking participants to ask "why" more often, and to ask for additional evidence before accepting someone's claims as being true
4. encourage employees to tinker
5. create opportunities for more curious and less curious individuals to work together in project based learning[10]

Final Thoughts

For the simple reason that employers are looking for people who do more than simply follow procedures competently or respond to requests, the truly curious will be increasingly in demand. We can all learn from Albert Einstein, who said that he had no special talents other than being passionately curious.[11] Fortunately, in a free society, no one can stop us from learning and there is no limit on the pursuit of knowledge.

References
1. Fernandez-Araoz C, et al. From Curious to Competent. Harvard Business Review. Sept-Oct. 2018.
2. Kidd C and Hayden BY. "The Psychology and Neuroscience of Curiosity." *Neuron*. 2015;88(3):449. DOI: 10.1016/j. neuron.2015.09.010.
3. Hardy JH, et al. "Outside the box: Epistemic Curiosity as a Predictor of Creative Problem Solving and Creative Performance." *Personality and Individual Differences*. 2017;104:230. DOI: 10.106/j.paid2016.08.004.
4. Matthias J, et al. "States of Curiosity Modulate Hippocampus-Dependent Learning via the Dopaminergic Circuit." *Neuron*. 2014. DOI:20.1016/j.neuron.2014.08.060.
5. Kasdan, T. Curious? Discover the Missing Ingredient to a Fulfilling Life. Harper Collins, New York, 2009.
6. Ibid.
7. Op cit 2.
8. Livio, M. Why? What Makes us Curious. Simon & Schuster, New York, 2017.
9. Leslie, I. Curious. Basic Books, New York, 2014.
10. Marilyn Price-Mitchell M. "Curiosity: The Force Within a Hungry Mind." February 2015. Edutopia website. https://www. edutopia.org/blog/8-pathways-curiosity-hungry-mind-marilyn-price-michell. Accessed 9 July 2019.
11. Op cit 5.

About the Author
Max Sherman is a retired regulatory professional. He has contributed to *Regulatory Focus* for more than two decades and is the author of the recently published book entitled "Eclectic Science and Regulatory Compliance: Stories for the Curious." The book contains 36 essays, most of which appeared in *Regulatory Focus*. In 2012, RAPS published "From Alzheimer's to Zebrafish: Eclectic Science and Regulatory Stories." He is also the editor of the first (2015) and second (2018) editions of "The Medical Device Validation Handbook." He may be contacted at maxsherman339@gmail.com.