

Reflections on the R



Regulatory Profession

Regulatory Focus asked several members of the inaugural class of RAPS Fellows how they have seen regulatory change, what the profession entails, and what advice they would give those in the profession to progress their careers. Those responding were Martha Carter, Bogdan Dziurzynski, Cheri Jones, Charma Konnor, Joyce Williams and Robert Yocher. This article presents their thoughts and opinions, reflecting insights from regulatory careers ranging from 20 to more than 30 years.

All agreed that the field has become far more complex over the past two decades. As noted by Yocher, this is “partially due to the complexity of the products and their technology, but also due to social and legal constructs associated with healthcare.” There also was recognition that regulatory now plays a far greater and more important role within the industry. One result of this, said Konnor, is that “more educational programs are available to regulatory professionals.” Also, this increased complexity is due in part to globalization in the healthcare products industry.

When asked what they found most rewarding in their careers, the predominant theme was the satisfaction of bringing a new healthcare product onto the market to benefit patients. There also was general agreement on the fact that the perception of the regulatory profession has improved over the years. However, the respondents believe there is still more to be done to increase awareness of the importance of regulatory professionals.

For those entering the regulatory field, the Fellows gave their opinions on what skills and knowledge are most valuable. They also offered their ideas on what constitutes success in regulatory and what forces impact the industry.

How has regulatory changed since you first started?

Martha Carter:

“It has changed enormously! Thirty years ago, regulatory was not recognized as a profession. In the private sector, people were often *displaced* into regulatory when a company did not know what to do with them. It was considered a paper-pushing job. There was little appreciation for regulatory’s strategic role. It has been through the actual failures (i.e., bankruptcies) of a number of companies that did not navigate the regulatory waters correctly that senior management has learned to take a different view of regulatory’s role. We are now seen by many, if not most,

companies as key members of senior management.”

Cheri Jones:

“The function is now more strategic than when I joined in the early 1980s. Today, regulatory is involved in planning functions in development and regulatory submissions, whereas 20 years ago the function was viewed more as clerical support with little strategic or scientific value to the company.”

Joyce Williams:

“It is much more technically complex and globally oriented. As well, while in the past there were clear distinctions between drug, device and biologic products, today there is a blurring of those categories. Thus, a regulatory professional now must be able to work across more than one of these areas, particularly as needed to support the very rapidly growing area of combination products. There is also a more strategic rather than tactical emphasis. These trends combine to require a better-educated individual with knowledge of operational and business concerns.”

Bogdan Dziurzynski:

“The regulatory arena has evolved over the years. The early years were shrouded in frequent ambiguity as a result of poorly defined procedures and processes, both at regulatory agencies and within the industry. Then there was recognition by all stakeholders that advancing public health through the development of new drugs, devices and diagnostic tools required better-defined regulatory requirements and consistent regulatory processes. In order to manage these regulatory complexities, there was a need to identify a regulatory professional who could serve as an expert in guiding technologies, companies and products through the development and approval process. Although, initially, on-the-job training was the primary avenue for regulatory staff development, the desire for a resource with the broad vision of providing cross-communication and -training in all the regulatory disciplines led to the establishment of RAPS as an essential tool for the profession’s growth and maturation. Regulatory procedures and processes are less ambiguous now and procedures are more consistent, but the regulatory arena remains a challenge for new technologies or significant modifications to existing methodologies. ‘First-in-class’ innovations challenge comfort levels and, therefore, thought processes.

When asked what they found most rewarding was the satisfaction of bringing a new healthcare



“Today, we see highly qualified regulatory professionals who have earned the respect of business colleagues and senior executives. The role of the regulatory professional is no longer limited to managing the assembly of regulatory documents. Today, there are senior regulatory professionals who have academic credentials that mirror those of the most qualified of our industry’s research scientists and have caused some companies to classify them as regulatory scientists. Some senior regulatory professionals have such strong business backgrounds that companies have appointed them as executive vice presidents and presidents. Regulatory professionals are being nominated by corporate officers and elected by shareholders to serve on boards of directors to ensure that companies have access to experienced counsel. Today, the regulatory professional is viewed as a vital member of the business team, and an integral component of and contributor to strategic planning and business efficiency.”

What advice can you give to someone just starting out in regulatory?

Konmor:

“Move through various departments to learn their functions; look for a mentor.”

Jones:

“Learn both the science and the business of the industry and the products. You will need both to be competitive and of the most value to both your organization and yourself.”

Dziurzynski:

“Anyone contemplating a new career in regulatory should take into consideration their qualifications, work ethic and career objectives. A prerequisite is the ability to work effectively with others at various levels within an organization. A bachelor’s degree in a relevant discipline is a minimum requirement; an advanced degree is preferred. Previous experience in a scientific environment can be a plus. The ability to make personal sacrifices of time and energy is essential to be successful. There will be frequent demands for your time during weekday evenings as well as on weekends to advance and complete projects on schedule and within budget. Recognize

that a regulatory career requires the highest personal integrity and strength of character to successfully choose between the right path and the expedient path. However, in spite of the challenges and sacrifices, a regulatory career can yield the most meaningful of rewards. Your personal sacrifices can lead to healthcare improvements that have a profound impact on public health. Your investment of self can lead to career advancement opportunities and participation in senior-level planning and decision making.”

Carter:

“It is a highly sophisticated, complex field. With the passage of myriad laws and regulations over the last 20 years, it is virtually impossible to learn everything one needs to know. The best way to gain experience is by doing; and starting on the lowest rung of the ladder will pay dividends later. That means actually putting submissions together; participating in team meetings to learn about the product and the challenges it faces; learning as much about the science of the product as possible, as science drives regulation; and always appreciating that poor decisions can have enormous and possibly fatal outcomes for our companies (therefore, use consultants as needed).”

Williams:

“Always be open to continual learning, since the requirements and policies of the regulators will frequently change. A strong science background is essential to enter the profession, but that must be combined with excellent writing abilities and presentation skills as well as an understanding of the broader development/operational issues confronting the industry.”

What do you find most rewarding about your profession?

Dziurzynski:

“Most rewarding for me has been the recognition that many of the products I’ve worked to make available have had a beneficial impact on the health and lives of patients and their families. The personal and professional growth I’ve experienced have only added to the feeling that my career in regulatory is meaningful and positive.”

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Carter:

“The ability to help put important new medical therapies into the marketplace is highly rewarding. Walking into a pharmacy and seeing a product on the shelf that you helped to develop and bring to market is an unbelievably satisfying feeling. Contributing to the success of our companies and with that, the well-being of our employees, is also very gratifying.”

Konnor:

“The breadth of knowledge and skills that are applied daily.”

Jones:

“The ability to help the company be successful in gaining new approvals, making changes to existing products or advising on strategies for introduction of other product lines.”

Williams:

“That we are working to bring new lifesaving medical products to patients.”

Yocher:

“It is most rewarding to know you have helped alleviate suffering, pain and disease, and were key in bringing help to those who really need it.”

Do you think regulatory requirements have become more or less globally harmonized during your career?

Dziurzynski:

“They have definitely become more harmonized. Global harmonization is an evolutionary and continuous process, but the progress to date has been significant.”

Carter:

“They have definitely become more globally harmonized. ICH didn’t exist when I started and, for that matter, neither did the EU! We have made great strides towards global harmonization, despite the fact that we still have a way to go.”

Williams:

“It has definitely changed toward more harmonization, particularly since the advent of the ICH

activities. In the past, there was a clear division of responsibilities between those working on US and on international product development activities. That is no longer the case, as most major regulatory authorities have harmonized requirements.”

Yocher:

“It is better but has a long way to go. Most recently, in the US, individual state laws are threatening to make regulations that will conflict with national law or create less harmonization, so it is not just a global issue.”

Konnor:

“Not sure; perhaps more harmonized, but there’s more work to do.”

Jones:

“The globalization of the world has indeed touched our profession as well. ICH in the early 1990s helped to emphasize the global nature of drug development, and as companies globalized, so did the roles of regulatory professionals.”

What do you think are the near-term roadblocks in the advancement of the profession?

Dziurzynski:

“I do not believe there are ‘roadblocks.’ However, I do believe there are professional challenges that must be addressed in order to continue to advance the reputation of regulatory professionals and the functions we perform. Many of these challenges are related to the skill sets of each individual. We must all develop the appropriate skills in order to be effective. There are several interrelated competencies that must be developed in concert. The most successful regulatory professionals exhibit high levels of expertise and knowledge in the areas of interpersonal communication skills, multitasking, leadership and management, business and personal ethics, sound decision making and judgment, strategic planning, honesty, openness to other ideas, consensus building, negotiation and an aptitude in business, the sciences and medicine.”



“Dedication, perseverance, and... even when things look impossible and...



Konnor:

“Getting CEOs and VPs to appreciate the need for qualified regulatory professionals, and employ them as such.”

Carter:

“I think there is still a perception that regulatory professionals are the policemen of a company. I think some still perceive regulatory professionals as being the roadblocks themselves or not adding value to their companies. We have, in part, brought that on ourselves. Also, the lack of a single educational pedigree for the job (e.g., science degree ± advanced degree vs. degree in some other discipline) makes it hard for those outside the profession to neatly pigeonhole us. I’m not sure there is a solution to that, however.”

Jones:

“That we were able to gain recognition of the profession as a strategic partner in management teams of companies tells me that the progress we worked so hard for is bearing fruit, and I really believe that the sky is the limit from here on out. So many regulators are sitting in the top levels of companies now that the next step would really be to the boardroom or other high-level decision-making positions in venture capital groups or the like.”

Yocher:

“I see the profession growing in importance despite the economy. I believe our industry will continue to be highly regulated and ever expanding. The educational system is recognizing this and is beginning to offer more degree programs. If anything, availability of experienced individuals might be a challenge but I do not see it as a roadblock. Price controls may be the biggest threat to the industry and subsequently to our profession.”

Williams:

“Regulatory professionals continually need to improve their technical and business background since the profession requires a blend of both skills. This may involve both more education and short-term training.”

What skill set would you be looking for when you hire someone into the profession?

Williams:

“Good oral and written communication skills; someone who has good project management skills and is deadline driven.”

Konnor:

“Good writer; quick study; ideally, at least some regulatory experience; and knowledge of the *FD&C Act*.”

Dziurzynski:

“Aptitude and demonstrated expertise in the skills mentioned above.”

Carter:

“Integrity, first and foremost. Eagerness to learn, ability to be flexible, inquiring mind and attention to detail are important. Good interpersonal skills and excellent organizational skills are a must!”

Jones:

“The first is common sense, a scientific foundation of some type coupled with regulatory knowledge upon which we could build. The ability to express oneself in either written or verbal form is required along with a personality that can not only be knowledgeable about the rules but also think out of the box to come up with novel solutions to hurdles encountered.”

Yocher:

“Experience in regulatory affairs, quality, project management, science and/or legal training, along with good communication skills, a good sense of ethics and a good sense of humor.”

How do you define success in regulatory?

Dziurzynski:

“Successful advancement of products into use by medical practitioners and patients. A track record of advancement in the profession coupled with the respect of colleagues and business leaders.”

drive and never ever giving up, and corporate deadlines seem daunting.”

Carter:

“Meeting corporate regulatory objectives, whatever they are. Unfortunately, we cannot consider ourselves to be successful regulatory professionals if our companies do not achieve success with respect to regulatory goals.”

Konnor:

“Being able to function, and be recognized, as a go-to regulatory professional—and helping others to succeed (mentoring).”

Jones:

“Achieving, through hard work and dedication, a level of trust and stature in both your company and the profession.”

Williams:

“There are many ways to measure success, but it should include helping to get innovative products to the market as soon as possible and always having a high degree of personal ethics.”

Yocher:

“Getting good medical products to markets where they are needed.”

What makes one successful in achieving regulatory milestones?

Dziurzynski:

“Good planning, decision making and leadership followed by effective communication, timeliness and high-quality execution of all tasks.”

Carter:

“This is a very important question. Too often, goals are set that are not realistic or achievable, and everyone suffers when that happens. First, the person setting the milestone must have a deep understanding of the regulatory context; therefore, good intelligence is critical. Second, she must have the respect of peers and superiors to be heard. Third, once identified, the regulatory professional must use those outstanding organizational and interpersonal skills to make sure the milestone (for example, a filing deadline for a new application) is met. A large regulatory submission is a highly complex task that requires

input from many people over a long period of time. It is not to be taken lightly! If the milestone is an approval, there is much that is beyond the control of the regulatory professional. In that case, understanding the regulatory landscape and communicating in real time with company senior management is highly important. In the startup world, financing can be contingent on meeting these milestones, so the stakes can be very high indeed!”

Konnor:

“Ability to work with others and to persuade others about the importance/significance of regulatory compliance.”

Jones:

“Dedication, perseverance, drive and never ever giving up, even when things look impossible and corporate deadlines seem daunting.”

Williams:

“Good project management skills, early involvement in a project, frequent communications with other involved departments and commitment to meeting timelines.”

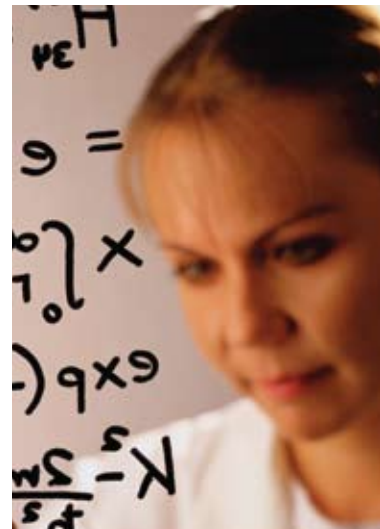
Yocher:

“Planning, perseverance, persistence and patience. But honestly, luck is sometimes involved.”

What external factors influence the regulatory profession?

Carter:

“Politics certainly affect our profession. I have been in the profession long enough to see the pendulum swing back and forth several times. An era of heightened regulatory oversight will eventually be replaced by an era of relaxed regulatory oversight, and the implications for our daily work and our ability to be successful in these different environments are not trivial. Each change of administration brings a new commissioner and a new focus. Unanticipated events, e.g., new safety findings for drugs or devices on the market, can have profound effects on our profession when they lead to new laws and/or regulations or perceptions. World events, e.g., epidemics and disasters like the



heparin contamination in China, can also affect us as they draw on the resources of regulators and command the attention of lawmakers.”

Dziurzynski:

“The dynamic nature of the field is influenced by advances in science, medicine and technology. The economy creates operational environments marked by either sustained growth or contraction of resources. Politics and public health perceptions help to define the parameters in which we function. The public perception of our institutions (both public and private) and how we perform ultimately determine how closely research, development, manufacturing and marketing functions are regulated and monitored. The field has experienced increased regulation in times of poor results or performance and greater flexibility during periods of more positive perceptions and performance.”

Konnor:

“The cost of doing business and compliance; these factors can work for or against regulatory.”

Jones:

“The merger and acquisition mode of the industry can lead to uncertainty regarding longevity in any one organization, but for those regulators who experience the disruption of moving to another position or company, it can be a positive as the opportunity to learn new product lines only adds to one’s knowledge base.”

Williams:

“Global marketing and product development trends; new safety issues (e.g., melamine, salmonella); and excitement and interest in development of new breakthrough therapies. Also, political influences can be important in setting priorities of the regulatory authorities.”

Yocher:

“Politics, information, misinformation and technology have, in my opinion, the most influence.” ■

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