ROCHE DIAGNOSTICS OVERVIEW

Greg Smith, Vice President, Diabetes Care Global Regulatory Affairs
Roche Diagnostics Corporation North America
## Agenda

### Intro
- Brief Intro to Roche (video)
- Brief Bio
- Relevance of Quality and Regulatory in Industry (video)
- The Challenges We Face

### Something For the Students
- Why Regulatory is Such a Great Field
- A Typical Day
- A Cursory Strategic Staircase to Make One An Attractive Candidate

### Something For the Faculty
- Highlights of the Program
- Taking the Program From Good to Great
- Potential Considerations for the Future Curriculum

### Take Home Message for All
- Testimonials
- Parting Thoughts
What Is Roche All About
A One Minute Overview
OUR PURPOSE

Doing now what patients need next

We believe it’s urgent to deliver medical solutions right now—even as we develop innovations for the future. We are passionate about transforming patients’ lives. We are courageous in both decision and action. And we believe that good business means a better world.

That is why we come to work each day. We commit ourselves to scientific rigor, unassailable ethics and access to medical innovations for all. We do this today to build a better tomorrow.

We are proud of who we are, what we do and how we do it. We are many, working as one across functions, across companies and across the world.

WE ARE ROCHE.
We are the world’s largest biotech company

WORLD LEADER in pharmaceuticals and in vitro diagnostics

COMBINED STRENGTHS in pharmaceuticals and diagnostics

HEADQUARTERS
Roche Group Headquarters in Basel, Switzerland
North America Diagnostics Headquarters in Indianapolis, Indiana

TOP FIVE companies, of any industry, for annual R&D spend
Roche’s Global Structure

48 BILLION CHF
GROUP SALES
IN 2015

PHARMACEUTICALS

ROCHE PHARMA
GENENTECH
CHUGAI

DIAGNOSTICS

MOLECULAR SOLUTIONS
CENTRALIZED & POINT OF CARE SOLUTIONS
DIABETES CARE
Global and U.S. IVD Diagnostics leader
Relevance of Quality and Regulatory at Roche and Elsewhere

A Short Video

- Ensuring The Right to Operate
- Driving Key Initiatives Supporting Game Changing Technologies
- Attracting, engaging, and retaining top talent
- Partnering with Agencies to Influence Regulatory Policy
- Driving Cost Efficient and Effective Process Improvements
Roche Diagnostics Regulatory Affairs Challenges We Face

The Perfect Storm

- Elevated recruiting costs during challenging times
- Forced to pay a premium for experience
- Many sought after external candidates may not accept
- 6-12 months to become fully proficient
- 4-12 months, on average, to fill positions
- Increasing demands to shape regulatory policy
- Ever-increasing no. of countries adopting MD Regs
- 4 US sites
- 2 Germany sites
- 1 Swiss site
- ~10-15 vacancies due to attrition/yr
- ~5-10 new positions/yr
- Pending retirements in next 1-5 years
- Projections for increased submission volume

...Leaving little doubt why the Purdue Program is so valuable!!!
# Purdue’s Masters of Regulatory Science Program

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A Career In Regulatory Affairs
Why It Is A Great Option

- Learning curve reduces field of qualified candidates
- The field is constantly evolving, so you never stop learning...and educating others
- Success aided by relationships you develop with Regulatory Authorities (not easily replicated)
- Your skills are in high demand...even more so when coupled with Quality experience
- Compensation tends to be commensurate with how valued your skill set is
- Regulatory roles tend to be highly visible within project teams and the entire organization
- Often provides exposure and expectations w.r.t. ROW cultures and Regulatory requirements
- More frequent sense of accomplishment (if serving multiple project teams)
- Allows for insight to most functions within an organization and then some...it’s never dull
A Career In Regulatory Affairs
An Opportunity To See The Whole Business and No Two Days Are Alike

Regulatory Affairs

- Affiliates/Countries
- Advocacy Groups
- Key Opinion Leaders
- Executive Mgmt
- Market Access
- Pharma/Partners
- Business Development
- Suppliers
- Customer Support
- Labeling
- Medical Affairs

- Research and Development
- Regulatory Authorities
- Quality Assurance
- Complaint Handling
- Quality Control
- Manufacturing and Process Development
- Marketing
A Career in Regulatory Affairs
Strategic Staircase for Acquiring Knowledge and Skills To Make One Attractive

**Foundational Elements:**
Tech. Knowledge, Excellent Oral/Written Comm. Skills, Influence/Negotiation Skills, Collaboration Skills, Resiliency, Self-Motivation, Operating in Gray Zone, Dealing w/ Difficult People, and Ability To See Around Corners

**Basic Regulatory Knowledge:**
510(k), PMA, Pre-Submissions, IVDR, MDR, ERCLs, IDEs, Supplemental and Annual Reports, EAP, RTA, SaMD, Combo Products, MDLs, MMAs, UDI/Labeling, Human Factors BLA, DeNovo…

**Applied Regulatory Knowledge:**
Demonstration of Foundational Elements and Basic Knowledge Areas, Collaborating with Regulatory Authorities, Satisfying Key ROW Reg Authorities (EU, Brazil, India, China, Russia), Shaping Policy, Site Inspections Rep.

**The Good News:**
These can be acquired thru:
- Undergrad coursework
- Purdue’s Masters Program
- Soft-Skills Courses
- RAPS
- Self-Study
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**Take Home Messages**

**For Students**
- Why Regulatory is Such a Great Field
- A Typical Day
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**For the Faculty**
- Highlights of the Program
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**Parting Thoughts**

- Why Regulatory is Such a Great Field
- A Typical Day
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Great learnings from engaging experts in the Quality and Regulatory fields

On-site classes is a huge advantage and appreciated

Working with (primarily) one team allows one to build relationships with and learn from one another

The strong emphasis on research forces one to thoroughly study a problem, critique published literature and formulate solutions.

The program’s global focus has instilled in me to not just consider the FDA but study regulations of the EU, APAC, ANVISA, etc.

On-campus weekend featuring Innovation as a statistician, Biomedical Engineering graduate projects, biosensors and their future and lastly the linkage between the supply chain and quality was most impressive/excellent.

Recognizing this program is still quite new, students report great strides improving the program in a very short period of time.

In class presentation from Ventana (applied) statistician made stats interesting

One of the best topics and projects we worked on, in my opinion, was the personalized medicine drug/reagent combination product. This was current, relevant, and interesting.
Remind students this is a graduate level program and they will only get out of it what they put in.

Commit to making course materials available at onset of class (not three weeks later)

Communicate assignments with a bit more daylight before being due

Post grades throughout the semester

Reduce overlap between courses. (No need for three different FDA mock inspections in different classes)

Several of the courses in the program focus solely on drug development and the drug industry...while interesting, it's not really directly applicable to our jobs in the medical device industry

Established professor office hours every week for remote student questions

Consider subtle tweak to mass spec weekend (possibly not quite so deep on the technical aspects...perhaps spend one day on technology and the next day on how to commercialize it/make it regulatory compliant)

Scheduling Webex's well in advance would be very helpful. This is especially important for the west coast students that have a three hour time difference to deal with and struggle to attend a Webex in the middle of the day.
Purdue’s Masters of Regulatory Science Program

Potential Considerations for the Curriculum

➢ Together with industry, conduct a comprehensive review of curriculum for subtle tweaks

➢ How regulatory life in the Medical Device and Pharma world differ

➢ Varied career opportunities in Quality and Regulatory Affairs and knowledge/skills to succeed

➢ GDP/GMP/GCP/Lab Controls

➢ Lean/Six Sigma

➢ Best practices for managing post-acquisition integrations

➢ Design control and regulatory submission requirements for Software and Health IT solutions

➢ Implications of IVD and MD recast

➢ Defending Your Quality System and Managing the Audit and Inspectors

➢ Understanding Quality System vulnerabilities in cases that are less black and white….Cases where a relatively good quality system is in place, but there are “gray zone” scenarios and how to remain compliant on a day-to-day basis
Purdue’s Masters of Regulatory Science Program
Potential Considerations for the Curriculum

- Companion diagnostics in personalized health
- Regulatory considerations around Good Promotional Practices
- Industry perspectives on complaint handling (and making student aware of the PreAmble)
- Consider additional emphasis on PMA best practices
- Assuming most soft skills already obtained from undergrad or work experience, consider class(es) focused on influence and debate
# Purdue’s Masters of Regulatory Science Program

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This program has provided exposure to areas within the organization that I wouldn’t have gotten otherwise, and it has been a great networking opportunity! I believe it was a large factor for why I was promoted into my current position. Often, jobs require specific experience that is difficult to get if you don’t already work in that area. It’s motivated me to think outside the box and understand how decisions in my current and previous roles could affect the rest of the organization. It’s also increased my own confidence and provided clarity for my career goals.

The program has provided me a broad and detailed perspective of the medical device and pharmaceutical industries. As a supplier quality engineer, I’ve used the knowledge gained from the class to enhance supplier management and perform better audits. Other skills acquired have enabled me to perform better program planning and risk assessments. Getting this strong regulatory training has depended my understanding of our regulated industry and gives me confidence my decisions are aligned with various regulations.

The insight that I have received through the instruction at Purdue has allowed me to understand the drug development process and the complexities around the process.
Purdue’s Masters of Regulatory Science Program

Testimonials

The BIRS program’s emphasis on the "larger picture" (including project management, quality, statistics, innovation...) directly prepared me for my new role as a CDx Project Leader, where I will be interacting not only with DIA, but also with various teams on the Pharma side including of course regulatory, but also the biomarker and clinical teams.

This program has been great for me personally. It directly addresses many of my developmental areas (regulatory intelligence, regulatory affairs, the clinical space) and brings really good foundational principles to the table that are always good to brush up on (project management, quality systems, supply chain).

This has been a great opportunity that I’ll forever be grateful for. There’s so much potential to make this a great program. It’s progressively gotten better, to the point that I’m almost sad I’m graduating instead of starting with the group last semester.

My 2 years in this program have directly led to doors being opened for new career opportunities and successes.
Purdue’s Masters of Regulatory Science Program

Testimonials

I have benefited from the program by having a deeper understanding of the regulatory submission process. I only had a high level understanding going into the program. Most of my direct experience was in Quality and Regulatory Compliance rather than Regulatory Affairs. We have completed several mock FDA submissions for devices (Class II and III), drug/device combos, and drugs. The repetition has been helpful to solidify knowledge. I have already used this knowledge in my current role. I am able to ask Regulatory Affairs colleagues more informed questions and more fully understand the complexities they face regularly. This helps deliver better launch plans and align the team.

We’ve been provided a great opportunity. The faculty have listened to our feedback and made adjustments.

I absolutely love the program and it is a highlight of my Roche experience. I am genuinely interested in the material presented and find the professors a wealth of information, knowledge and enthusiasm.

I feel the program directors are willing to do what is necessary to make it a "great" program. I am very grateful to have the opportunity to be in the program.
Purdue’s Masters of Regulatory Science Program
Parting Thoughts

- This is not so much about obtaining a degree
- This is more than teaching and learning about Quality and Regulatory
- This is about assuming a lead role in keeping a business viable
- This is about providing one with the opportunity to be excited about their daily job and career
- This is, at some point, likely about saving and/or improving your life or the lives of someone close to you
- This is about having a positive impact on society and, by some standards, a higher calling

Both as students and faculty, you can and are making a huge contribution to these ideals!