March 21-22, 2018
Hilton Boston Back Bay | Boston, MA

8th

CMO QUALITY OVERSIGHT & RISK MANAGEMENT SUMMIT

Fortify Quality and Ensure Compliance Through Robust Conversations About Cultural Implications and Transference

FEATURED SPEAKERS

Sonali Balwani
Quality Control, Lead
ADVAXIS

Joseph Kudla
Associate Director, QA Operations/Systems
ASTRAZENECA/ MEDIMMUNE

Natasha Bussard
Manager Product Development, R&D
UPM PHARMACEUTICALS

Suzanne Murray
VP of Quality
AGIOS PHARMACEUTICALS

Sandra Edwards
Director, Corporate Quality Compliance and Risk Management
TARO PHARMACEUTICALS

Michelle Bailey
Associate Director, Validation for Continuous Manufacturing and Automation
VERTEX

Julia N. Hart
Head of Quality
APTEVO THERAPEUTICS

Eyad Salman
Principal Quality Site Manager
GENENTECH

Nadine Jahn
Senior Manager, Third Party Quality Management
BOEHRINGER INGELHEIM

Wendy Summers
Director of Quality
CHIESI USA

Laura Kalegaric
Associate Director, Quality Assurance
AKEBIA THERAPEUTICS

Eva Urban
Senior Manager, OpEx Risk Management
CELGENE

WHAT'S NEW FOR 2018?

This year's program features all new educational spotlights, case studies, and panel sessions on the following topics:

- Ensure data integrity through judicious selection, contracting and governance
- Effect technology and method transfer and assess success with suitable KPIs
- Surmount barriers to Quality resulting from cultural discord
- Avoid findings through audits according to inspection trends
- Streamline monitoring of performance and process for a drug or combination product
- Anticipate and mitigate risk through prevention and preemptive detection
- Ensure CMO capability and suitability by co-opting tried and tested tools and metrics

"World-class presentations from senior leaders. Really worthwhile to attend and will encourage my staff to attend next year."

—QA Director, Genzyme External Manufacturing, **SANOFI BIOLOGICS**

8th CMO QUALITY OVERSIGHT & RISK MANAGEMENT SUMMIT

Dear Colleague,

Pharmaceutical and biotech companies rely on external contact organizations to develop and manufacture their drugs. The complexity brought about by increasing regulations is amplified by the urgency that is created by emerging markets, globalization, increased competition, and the advent of continuous manufacturing, among other stressors. Now more than ever, having effective quality oversight and risk management strategies in place is crucial when ensuring successful partnerships, especially while doing business globally.

ExL's 8th CMO Quality Oversight & Risk Management Summit brings together Quality experts from sponsors and CMOs for rigorous discourse and learning that focuses on ensuring compliance and fostering a culture of Quality. A mutual understanding of the risk involved for each project and a transparent working relationship are key prerequisites for a successful sponsor-CMO partnerships. This conference offers a toolkit to prevent GMP failures that would result in corrective action.

This year's program features all-new educational spotlights, case studies and panels to illuminate best practices related to:

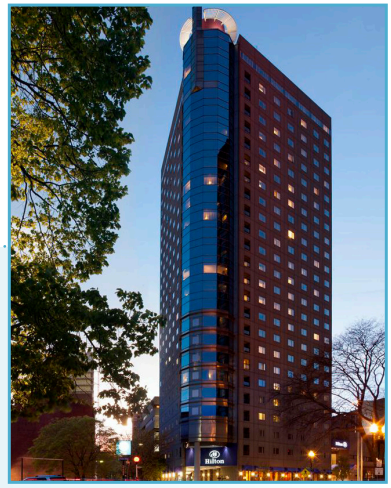
- Replicating best practices for technology and method transfer
- Ensuring data integrity and compliance with regulations
- Mastering metrics for compliance and a competitive edge
- Drafting contracts and Quality Agreements that assure success
- Selecting the right supplier or CMO for emerging or start-up
- Identifying and minimizing risks of a CMO by implementing Quality by Design

I look forward to seeing you in Boston this spring.

Sincerely,

Brian

Brian L. Anderson
Senior Conference Producer



Venue

Hilton Boston Back Bay
40 Dalton St. | Boston, MA 02115

To make reservations, please call 617-236-1100 or 1-800-HILTONS (445-8667) and request the negotiated rate for **ExL's 8th CMO Quality Oversight & Risk Management Summit**. You may also make reservations online using the following url address http://bit.ly/2B0pjNZ. The group rate is available until **February 27, 2018** Please book your room early, as rooms available at this rate are limited.

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WHO SHOULD ATTEND?

This conference is designed for professionals from pharmaceutical, biotech, medical device companies and CMOs with responsibilities in the following areas:

- Quality Assurance/Quality
- External/Contract Manufacturing
- Regulatory Affairs/Compliance
- Manufacturing Operations
- Product/Device Management
- Technology Transfer
- Supply Chain Management
- External Supply/Supplier Quality
- Technical Operations
- Contract Development
- Manufacturing Operations
- Outsourcing/Strategic Sourcing
- Process Development/Optimization
- CMC Operations/Chemical Development
- Procurement
- Risk Management
- Biologics
- API Development
- Tech Development
- Supply Operations

This conference is also of interest to:

- Pharma Contract Manufacturing Service Providers
- CMO Auditing Software Organizations
- Regulatory/Compliance Consultants
- Vendor Selection/Management Software Providers
- Compliance Software Companies
- Quality Manufacturing Service Providers

Sponsorship and Exhibit Opportunities

Do you want to spread the word about your organization's solutions and services to potential clients who attend this event?

Take advantage of the opportunity to exhibit, present an educational session, host a networking event, or distribute promotional items to attendees. ExL works closely with you to customize a package that suits all of your needs.

8:00 Registration and Continental Breakfast Begin

9:00 Chairperson's Opening Remarks

9:15 **Carousel: Discussion Exercise**

This conversational forum is ideal for sharing and discussing best practices. Each group is assigned a different topic. Group members list and discuss their collective practices. After 20 minutes, groups begin a rotation in which they spend 10 minutes reading other groups' recorded practices before adding their own. The end product is a digest of participants' best practices in the following categories:

- Collaboration
- Metrics
- Governance/Management
- Technology Transfer

10:15 **Ensure Quality Through Effective Relationship Management and CMO Support**

- Establish clear expectations with clear communications backed up by Quality Agreements
- Conduct audits and weekly meetings as supportive enterprises to foster improvement
- Achieve representation of all functions (e.g., regulatory, analytics, formulation, etc.) on internal Quality-driven teams
- Earn "Quality" a central place at the table with legacy and new CMO contracts
- Couple collaborative approaches with necessary structures, determining and effecting necessary change

Natasha Bussard, *Manager Product Development, R&D,* **UPM PHARMACEUTICALS**

Laura Kalegaric, *Associate Director, Quality Assurance,* **AKEBIA THERAPEUTICS**

11:00 Networking Break

11:30 **Support Inspection and Audit Readiness Through Culturally Sensitive Oversight and Management**

- Manifest Quality by recognizing cultural imperatives
- Look at critical components of a vendor management plan
- Amplify improvement with an enhanced understanding of culture's impact on Quality
- Manage the supply chain in coordination with the whole group
- Perform GXP audits to qualify external testing laboratories

Sonali Balwani, *Quality Control, Lead,* **ADVAXIS**

12:15 Luncheon

1:15 **Assure Quality With Collaborative Ventures From Disparate Deal Types**

- Co-opt practices from a Supplier Quality System Model for other third-party contractual partnerships in Clinical Development
- Assess risk and adapt operations accordingly to mitigate risks
- Learn how your supplier quality model/system can be hybridized for various relationships
- Compare QA systems of CMOs and Collaborative Ventures at MedImmune

Joseph Kudla, *Associate Director, QA Operations/Systems,* **ASTRAZENECA/MEDIMMUNE**

2:00 **Case Study: Mitigate Risk Through Cultural Change and Mindset Management**

CASE STUDY

- Discuss types of risk and red flags that may be early indicators of different types of risk
- Improve Quality through training, accommodations and interventions that impact culture
- Convey purpose, promote empathy and imbue mission to improve Quality
- Evaluate your audit program for its viability for risk attributions
- Examine case examples of interventions that made a difference

Wendy Summers, *Director of Quality,* **CHIESI USA**

2:45 **Case Study: Avoid Surprises by Performing Robust Due Diligence in Partner Selection**

- Understand the CMOs processes and management philosophy via RFP, site visits, meetings, tours, etc. with a cross-functional team during due diligence
- Align with your CMO on culture, processes and operations and incorporate into your partnership arrangements
- Discuss case examples of flourishing vs discordant partnerships and their respective attributions and challenges
- Review essential questions and priorities for selection based on capability

Suzanne Murray, *VP of Quality,* **AGIOS PHARMACEUTICALS**

3:30 Networking Break

4:00 **Case Study: Hear Celgene's Approach to Streamlining Procedures**

CASE STUDY

- Improve efficacy through optimal team composition and workflow
- Give the customer a voice and practice customer-driven thinking and improvements
- Assess the continuous improvement-risk assessment options from different angles in the team(s)
- Develop and leverage appropriate tools and assessments for different purposes
- Consider relatable communications and change management tactics and metrics for determining impact

Eva Urban, *Senior Manager, OpEx Risk Management,* **CELGENE**

5:00 **Maintain the Top Position on Your CMO's Priority Ladder**

- Establish well-defined lines of communication with new and legacy CMOs
- Leverage specialized joint project and management teams
- Motivate CMOs from day one as critical project stakeholders
- Forge positive relationships with key CMO personnel
- Execute meaningful Quality Agreements as a road map to successful collaboration

Julia N. Hart, *Head of Quality,* **APTEVO THERAPEUTICS**

5:45 Day One Concludes

"Great topics, experienced leaders, no 'redundant' presentations on same subject matter."

—**Brid Rooney,** *QA Director,* **SANOFI BIOLOGICS**

Thursday, March 22, 2018

Day Two

8:00 Continental Breakfast Begins

9:00 Chairperson's Recap of Day One

9:15 **Compare and Contrast Technical (Quality) Agreements Guidelines in the U.S. and the EU**

- Discuss the universal components and common components of Quality Agreements
- Explore guiding principles of developing a sound template
- Gain insight into the general setup and a table of contents of BI's QAA template
- Avoid pitfalls by identifying nuanced challenges of regulatory within multiple regions
- Discuss the merits and disadvantages of flexibility within a QAA from the perspectives of quality oversight and compliance

Nadine Jahn, *Senior Manager, Third Party Quality Management,* **BOEHRINGER INGELHEIM**

10:00 **Case Study: Discuss CMO-Owner Collaboration in Continuous Manufacturing That Maintains Quality While Maximizing Savings**

CASE STUDY

- Move from discontinuous to continuous to validate your methodology for quality results
- Collaborate with suppliers and CMOs for CM program build-out
- Identify and address risks to Quality and validation and how the contracts and validation documentation can mitigate those risks
- Understand regulatory inspection concentration areas for CM

Michelle Bailey, *Associate Director, Validation for Continuous Manufacturing and Automation,* **VERTEX**

10:45 Networking Break

11:15 **Achieve Organizational Excellence and a Culture of Quality: Medtronic's Approach**

- Understand why a Quality-centric culture is so vital to sustained outcomes
- Look at the correlation between quality culture and organization performance
- Learn how FDA is driving organizational excellence and quality culture focus: Manufacturing Site Capability Assessment (CMMI®) pilot programs and potential benefits
- Discuss viability and benefits of assessing culture
- Learn about "Quality Begins with Me": Medtronic initiative

Prakash Patwardhan, *Director of Corporate Quality,* **MEDTRONIC**

12:00 **Negotiate a Quality Agreement, As a Supplier, With a Business Partner That Has Licensed Your Drug**

- Prepare for shortages in the event of a shutdown
- Recognize warning signs and other indicators
- Conduct a risk-based assessment and take precautions
- Offer incentive-based contract to ensure Quality

Amnon Eylath, *Senior Director, Quality Assurance,* **GENZYME**

12:45 Luncheon

1:45 **Explore the Difference Between Quality Agreements and Contract Manufacturing in the U.S. and Canada**

- Survey the components of Quality Agreements — Canada vs. USA
- Discuss which parts are emphasized by different constituencies in different regions (e.g., regulators, CMOs, internal stakeholders)
- Understand the Canadian requirements for establishment licensing as it relates to product importation and compliance
- Hear about Canadian inspections and contract manufacturing
- Drill down to the expectations of change controls and technical transfer components of QA

Sandra Edwards, *Director, Corporate Quality Compliance and Risk Management,* **TARO PHARMACEUTICALS**

2:30 **Case Study: Study Lessons Learned in Tech Transfers in Emerging Markets**

CASE STUDY

- Get an overview of the emerging market landscape and survey what's on the horizon
- Discover and explore opportunities
- Delve into inherent risks and challenges (e.g., cultural, linguistic, technical, etc.)
- Study case examples and practices that have worked in emerging markets
- Hear what improvements have resulted from lessons learned

Eyad Salman, *Principal Quality Site Manager,* **GENENTECH**

3:15 Chairperson's Closing Remarks

3:30 Conference Concludes

"This conference has provided me with useful tools and different perspectives that will allow me to successfully transfer drug products."

—**Nicole Zinzi,** *Manufacturing Process and Technology Associate,* **REGENERON**

"Excellent group size. Experienced attendees."

—**Cameron Jones,** *QA Director,* **BRAMMER BIO**

"All talks were relevant to my role and I gleaned a few items to consider/discuss with my team from each speaker. FDA speaker +++"

—**Nuha Al-Hafez,** *Head, External Supply Quality Group,* **MERCK**

"Can't wait to apply lessons learned in CMO Quality Management. Extremely valuable content relevant across drug and therapeutic manufacturing platforms."

—**Michael Gargiulo,** *Quality Manager, External Manufacturing,* **VALEANT**

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