“What’s New for 2016?“

Driving a Culture of Quality through effective oversight and risk mitigation strategies

Identifying lessons learned from small to mid-sized sponsor companies partnering with large CMOs

Overcoming communication and cultural barriers when outsourcing to CMOs in emerging markets

Considering data integrity while preparing for an inspection

Spearheading effective technology transfers to CMOs based on QbD principles

Analyzing the latest FDA rulings for quality metrics and their impact on outsourcing

Our Distinguished Speaker Faculty Includes:

Scott Duncan, Director of Chemistry, STEALTH BIOTHERAPEUTICS

Emma Newman, Lead, QA IT, SHIRE

Puthucode N. Rajamani, President, RAJAMANI GROUP LLC

Lisa Thimmesch, Customer Quality Manager, ONE 2 ONE™ GLOBAL PHARMACEUTICAL SERVICES

Jonathan Patroni, Head, US Quality, SHIRE

Greg Birrer, Ph.D., Senior Director, Quality, ELUSYS THERAPEUTICS

Denise McDade, Vice President, Quality, CAPRICOR

Amnon Eylath, Vice President, Quality, HISTOGENICS

Dale Herbranson, Ph.D., Vice President, Quality and Regulatory - Tech Group, Contract Manufacturing, PDS Division, WEST PHARMACEUTICAL SERVICES, INC.

Wanda Tormos, Senior Manager, Chemical Development Strategic Outsourcing, GILEAD

Heidi Hoffman, Senior Director, Manufacturing, SUTRO BIOPHARMA

Eyad Salman, MSQA, Principal Quality Site Manager, Emerging Markets PTQBXE-JMT Project Reach Quality Lead, GENENTECH/ROCHE INDIA

Sponsored By: ONE2ONE
Dear Colleague,

Contract Manufacturing Organizations (CMOs) have proven to be valuable for the biopharmaceutical industry. From virtual biotechs to Big Pharma, organizations of all sizes are implementing outsourcing programs for a variety of reasons. As the life science industry continues to evolve, more and more drug developers are outsourcing some or all of their development and manufacturing to contract manufacturing, development, research and laboratory organizations. The biopharma contract manufacturing market continues to expand and is projected to grow 8% by 2020, according to research by HighTech Business Decisions.

Now more than ever, effective quality oversight and risk management strategies are non-negotiable requirements to ensure successful partnerships, both in the US and overseas.

The 6th CMO Quality Oversight & Risk Management Summit will help attendees identify and implement best practices to enhance partnerships between sponsors and CMOs. Further, the Summit serves as a networking platform for quality and compliance professionals to connect and discuss the latest trends in outsourcing. Finally, this event provides the strategic insights and expertise necessary to navigate the evolving regulatory landscape across the entire outsourced life cycle to ensure that necessary products are available to the patients who need them.

This year’s program features new educational spotlights, case studies and interactive panel sessions on:

- Driving a culture of quality, innovation and productivity through effective oversight and risk mitigation strategies
- Simplifying your contract manufacturing process without sacrificing quality or project costs
- Overcoming communication and cultural barriers when outsourcing to CMOs, particularly in emerging markets
- Considering data integrity and other health authority key focus areas while preparing for an inspection
- Studying the latest FDA rulings for quality metrics and their impact on outsourcing
- Drafting mutually beneficial and creative contracts and quality agreements that incentivize CMOs

Join industry leaders and quality professionals to discuss best practices for successful CMO management and partnerships.

WHO SHOULD ATTEND:
This conference is designed for professionals from pharmaceutical, biotech, medical device and clinical research organizations with responsibilities in the following areas:

- Quality Assurance
- External Contract Manufacturing
- Manufacturing Operations
- Product Quality
- Auditing
- Risk Management
- Regulatory Affairs/Compliance
- Technology Transfer
- Process Development/Optimization
- Outsourcing/Strategic Sourcing
- Supply Chain
- Operational Excellence
- Compliance/GMP Compliance
- API Development
- Biologics
- Product Development

This conference is also of interest to:

- Pharma Contract Manufacturing Service Providers
- CMO Auditing Software Organizations
- Regulatory/Compliance Consultants
- Compliance Software Companies

Venue Information:
SHERATON BOSTON HOTEL, BOSTON, MA
39 Dalton Street
Boston, MA 02199

To make reservations please call 1-888-627-7054 and request the negotiated rate for ExL’s April 2016 Meeting. You may also make reservations online using the following link: http://bit.ly/1Oiz1p9.

The group rate is available until March 29, 2016. Please book your room early as rooms available at this rate are limited.

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Day One
Wednesday, April 20, 2016

8:00 Registration and Continental Breakfast

9:00 Co-Chairpersons’ Opening Remarks
   Tim Scott, President, PHARMATEK
   Stan Russell, Head of Quality - Partnerships, BAXALTA

9:15 CMO SPOTLIGHT
   Drive a Culture of Quality at Your CMO
   • Recognize quality as the most important factor at your CMO
   • Drive employee engagement for enhanced quality and production
   • Implement an effective internal CMO management structure
   Tim Scott, President, PHARMATEK

10:00 PANEL DISCUSSION
   Evaluate Preliminary Outsourcing Considerations
   • Hear from sponsor, CMO and regulatory professionals on major factors to consider when deciding to outsource
   • Understand financial considerations, e.g., direct and “hidden” costs to a manufacturing project
   • Evaluate how outsourcing to a CMO may impact expected revenue when going to market
   Heidi Hoffman, Senior Director, Manufacturing, SUTRO BIOPHARMA
   Wanda Tormos, Senior Manager, Chemical Development Strategic Outsourcing, GILEAD
   Amnon Eylath, Vice President, Quality, HISTOGENICS

11:00 Networking Break
   Sponsored by ONE 2 ONE™ Global Pharmaceutical Services

11:30 Get a CMO’s Perspective on Contracts, Risk and Metrics for Success
   • Understand the challenges CMOs face regarding contract negotiations, liability and risk assessment – and why it matters to you
   • Explore why conforming to a CMO's quality system helps safeguard your medicine
   • Discover how mutual metrics for success can reduce risk and increase quality
   Lisa Thimmesch, ONE 2 ONE™ Quality Manager, HOSPIRA, a PFIZER company

12:15 Luncheon

1:15 DATA SPOTLIGHT
   Consider Data Integrity While Preparing for Inspection
   • Adapt with industry reliance on computerized systems and understand the criticality of data to patient safety and product quality
   • Gain practical guidance for auditing contract organizations and address data integrity audit considerations
   • Discuss the new MHRA Guidance on Data Integrity and relevant regulatory observations
   • Assess what we are really looking for: intentional versus unintentional, risk-based assessments and technical limitations
   • Consider the use of IT cloud vendors, and the controls that should be in place
   Jonathan Patroci, Head, US Quality, SHIRE
   Emma Newman, Lead, QA IT, SHIRE

2:00 CMO SPOTLIGHT CASE STUDY
   Evaluate the Supplier Management Process for a CMO of Combination Products
   • Develop a risk-based and structured approach to managing suppliers while manufacturing devices
   • Establish a risk analysis profile for suppliers
   • Scale the risk process based on the customer’s individual needs
   Dale Herbranson, Ph.D., Vice President, Quality and Regulatory - Tech Group, Contract Manufacturing, PDS Division, WEST PHARMACEUTICAL SERVICES, INC.

2:45 Networking Break

3:15 Implement Best Practices for Risk Identification and Management at a CMO
   • Understand how risk management can be an integral part of how CMOs are monitored
   • Present a tool that shows how risks are captured and managed
   • Facilitate risk review and the evaluation and identification of risks, and establish how communication with a CMO is an integral part of risk reduction
   Eyad Salman, MSQA, Principal Quality Site Manager, Emerging Markets PTQBX-E-JMT Project Reach Quality Lead, GENETECH/ROCHE INDIA

4:00 EMERGING MARKETS SPOTLIGHT
   Address 21st Century Skills for Managing Pharmaceutical Professionals in the Drug/Biotech Industries While Working with Partners in Emerging Markets
   • Examine 24 soft skills for improved dialogue and communication with your CMO partners
   • Build cross-cultural effectiveness to understand cultural knowledge and awareness
   • Review guidelines for communication and overcoming related barriers
   Puthucode N. Rajamani, President, RAJAMANI GROUP LLC

4:45 Day One Concludes

“Very stimulating and thought-provoking presentations. Excellent!”
—Senior Quality Director, MALLINCKRODT PHARMACEUTICALS

“Great to have the CMO perspective!”
—QA Manager, NOVARTIS
Day Two
Thursday, April 21, 2016

8:00 Continental Breakfast

9:00 Co-Chairpersons’ Recap of Day One
Tim Scott, President, PHARMATEK
Stan Russell, Head of Quality - Partnerships, BAXALTA

9:15 PANEL DISCUSSION
Quality Agreements and Multilevel Contracts when Working with a CMO
- Ensure transparent communication is in place between the sponsor and CMO for quality and risk management
- Ascertain a process for communicating new and existing risks through a process diagram
- Identify red flags for product quality issues and develop proactive mitigation strategies
- Maintain control and transparency through the manufacturing process
- Examine the amount of risk sponsor companies think CMOs add

Stan Russell, Head of Quality - Partnerships, BAXALTA
Scott Duncan, Director of Chemistry, STEALTH BIOtherapeutics
Dale Herbranson, Ph.D., Vice President, Quality and Regulatory - Tech Group, Contract Manufacturing, PDS Division, WEST PHARMACEUTICAL SERVICES, INC.

10:15 CASE STUDY
Discuss Quality Oversight of CMOs from a Small Virtual Sponsor Perspective
- Hear a case study about a small, fully virtual biotechnology company’s experience with sponsor quality oversight of large CMOs
- Present best practices for a successful partnership with CMOs
- Describe quality’s role in selection, qualification, performance and issue identification with CMOs
- Review key aspects of communication and methods of interaction to foster closer working relationships between companies and quality personnel

Greg Birrer, Ph.D., Senior Director, Quality, ELUSYS THERAPEUTICS

11:00 Networking Break

11:45 CASE STUDY
Assess the Feasibility, Benefits and Risks of Using Contract Manufacturing for Cell Therapies
- Understand the special needs of cell therapy startup companies
- Learn the capacity drivers for production scale-up and commercialization, including globalization
- Evaluate how contract manufacturers meet the operational and compliance requirements for cell therapy operations
- Know what to look for in a contract or partnership relationship when exploring CMOs
- Identify the challenges of technology transfers for cell therapies
- Weigh the pros and cons of using a CMO for cell therapy

Amnon Eylath, Vice President, Quality, HISTOGENICS

12:15 Luncheon

1:15 Streamline Procedures for Monitoring Process Performance and Product Quality
- Establish preliminary standards while contracting with a CMO to ensure GMP compliance
- Define objectives and communication processes between the CMO and sponsor company
- Identify key metrics and measurements to standardize quality
- Review the legal requirements and limitations to consider
- Implement procedures for monitoring process performance and product quality
- Issue performance measurements with economic benefits and penalties for the supplier and the CMOs

Denise McDade, Vice President, Quality, CAPRICOR

2:00 Drive an Effective Technology Transfer to CMOs Based on QbD Principles
- Integrate information systems between CMO and sponsor
- Learn how much variability a CMO will introduce to a validated QbD process
- Ensure that end products align with expected results
- Manage the pipeline to ensure that CMOs have the right technologies in place
- Guarantee that the CMO has similar lab equipment and the same measurement practices

Adnan Sabir, QA CMC Manager, KOWA PHARMACEUTICALS

2:45 CASE STUDY
Discuss the Darker Side of Flexible Infrastructure
- Recognize negative outcomes related to the flexible infrastructure approach of CMO management at smaller companies
- Hear several case studies on the flexible infrastructure at smaller companies and understand how this approach can be resource intensive and costly in terms of time and money

Scott Duncan, Director of Chemistry, STEALTH BIOtherapeutics

3:45 Co-Chairpersons’ Closing Remarks
Tim Scott, President, PHARMATEK
Stan Russell, Head of Quality - Partnerships, BAXALTA

4:00 Conference Concludes

“Excellent audience engagement, great topics and discussion. A very useful conference.”
—Director, Quality, MALLINCKRODT PHARMACEUTICALS

“Very engaging, fresh approach!”
—Vice President, Quality, WEST PHARMACEUTICALS
Registration Fees:

**EARLY BIRD PRICING**
Register by March 4, 2016
$1,895

**STANDARD PRICING**
Register After March 4, 2016
$2,095

**ONSITE PRICING**
$2,195

*Includes Sales Tax and Service Fees

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To receive a refund or voucher, please contact our offices at (201) 871-0474.

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