New for 2014:

- **REGULATORY UPDATE:** Find out about the vital updates to FDA guidance *Contract Manufacturing Arrangements for Drugs: Quality Agreements* and revise quality agreements accordingly

- **ALIGN QUALITY SYSTEMS:** Cultivate quality standards and common understandings of regulatory interpretations to create harmonized systems internally and externally to ensure quality and GMP compliance

- **RISK ASSESSMENTS:** Identify relevant risk categories and develop a risk assessment table to compare CMOs to manage risk and protect your supply chain

- **GENENTECH CASE STUDY:** Establish risk ranking and profiling of suppliers to mitigate risk and roll out contract quality requirements to drive continuous improvement

- **MEDIMMUNE CASE STUDY:** Develop and implement a supplier relationship management process to advance process improvement

Featuring New Case Studies From:

- **Jonathan Patroni**
  Head of North America Quality Assurance, Technical Operations, SHIRE

- **Lee Fox**
  Third Party Manufacturing Quality Manager, BRISTOL-MYERS SQUIBB

- **Todd Mabe**
  Head of Biologics, Drug Substance, External Quality, PTQBX, ROCHE

Distinguished Speaker Faculty Includes:

- **Brian Clark**, Executive Director, Quality, IMMUNOGEN, INC.
- **Scott Duncan**, Senior Staff Scientist, Chemical Development, ALKERMES
- **Amnon Eylath**, Senior Director Quality Assurance, GENZYME CORPORATION
- **Madeline Fisher**, Director, Supplier Quality Management, MEDIMMUNE - A DIVISION OF ASTRAZENECA
- **Prasad Gogineni**, Director, Operations, ACTAVIS
- **Mike Gross**, Senior GMP Compliance Auditor, BIOGEN IDEC
- **Nelson M Lugo**, Senior Director, Contract Manufacturing, AMYLIN PHARMACEUTICALS, LLC (a wholly owned subsidiary of Bristol-Myers Squibb)
- **James Nelson**, Senior Director, Quality Assurance, ARENA PHARMACEUTICALS
- **Dan Trimberger**, Director, Quality Assurance, MOMENTA PHARMACEUTICALS

To Register: Call 866-207-6528 | Visit www.exlpharma.com/CMO | Email registration@exlpharma.com
With the global CMO market expected to generate revenues of $60 billion by 2018, the time has never been more critical to implement comprehensive strategies for robust quality oversight of external manufacturers to ensure GMP compliance and avoid the lofty costs of potential product recalls, consent decrees and adverse events.

Manufacturing Quality is under heavy scrutiny by the FDA and regulatory authorities globally. The FDA has been known to issue warning letters to sponsors when quality agreements haven’t been in place, and to put additional pressure on drug makers, the agency released new guidance on quality agreements in May to ensure sponsors outline responsibilities up front for both parties. Furthermore, the industry is experiencing rampant product recalls and GMP failures, particularly in China and India. Are your strategies for quality oversight robust enough to track and prevent GMP failures, which could result in product recalls, adverse events and plant closings?

ExL Pharma’s 4th CMO Quality Oversight & Risk Management Conference is the only opportunity to gain best practice strategies to effectively oversee and manage quality of contract manufacturers to ensure GMP compliance in an evolving regulatory landscape. Gain critical updates on the new FDA guidance for quality agreements as well as the practical knowhow to revise quality agreements to reflect new guidance and be prepared for reporting and inspections.

Quality and manufacturing professionals working across industry will help you to:

- Align quality systems across multiple CMOs to ensure consistent high quality
- Know which gaps to look for in quality systems of vendors during CMO selection to determine if a manufacturer will have quality failures
- Administer comprehensive risk assessments to assess, manage and mitigate risk to protect your supply chain
- Gather and collect evidence to demonstrate thorough management of outsourcing operations to be prepared for and ready for your next FDA inspection
- Understand how to alleviate and reduce risk during process validation activities
- Import quality metrics and KPIs to examine levels of acceptable risk as part of a continuous improvement strategy

Take away a complete toolkit of tried and tested methods for CMO selection, auditing procedures, risk assessment and management, quality system alignment, inspection readiness as well as frameworks to implement continuous improvement within harmonized systems to improve quality, reduce cost and increase profitability.

Who Should Attend:

This conference is specifically designed for pharmaceutical, biotech and medical device professionals specializing in:

- Quality Assurance
- External Manufacturing / Contract Manufacturing / Third Party Manufacturing / CMC
- Manufacturing Operations
- Product Quality
- Auditing
- Risk Management
- Regulatory Affairs / Compliance
- Technology Transfer
- Process Development / Optimization
- Outsourcing
- Supply Chain
- Operational Excellence

This event is also of interest to professionals from multiple-sized CMOs specializing in:

- Business Development
- Quality
- Technology Transfer
- Product Development
- Licensing
- Regulatory Affairs

Hotel Information

**Hyatt Regency Boston**

One Avenue De Lafayette, Boston, MA 02111 Tel: 1-888-421-1442

If you require overnight accommodations, please contact the Hyatt Regency Boston at 1-888-421-1442 to book your room. ExL Pharma has reserved a block of rooms at a discounted rate for conference participants. Please mention ExL Pharma’s 4th CMO Conference to take advantage of the discount. You must book your room by April 1st, 2014 to be eligible for the discounted rate. Please book your room early, as the rooms available at this rate are limited.

To Register: Call 866-207-6528 | Visit www.exlpharma.com/CMO | Email registration@exlpharma.com
Day One  Wednesday, April 23, 2014

8:30  Registration and Continental Breakfast for Workshop Participants

9:30  Robust and Effective Auditing Procedures of CMOs for Stringent Quality Oversight

Auditing programs are an integral tool for quality oversight of suppliers. Failure to execute rigorous and thorough audits could result in missing lapses in quality systems, gaps in training, problems with facilities and improper documentation. Do you have an auditing checklist? Are you confident that your auditing procedures will identify GMP failures and ensure providers are maintaining appropriate quality standards every time?

This workshop will help you to:

- Understand when to audit, duration of audit and the appropriate audit team
- Know the documents required when the FDA begins an audit
- Review SOPs, quality management systems and training and qualification of staff
- Develop a schedule for periodic audits throughout the lifecycle of the contract
- Produce audit reports including high-level summaries of audit findings in a timely fashion

Prasad Gogineni, Director, Operations, ACTAVIS
Jim Damon, Formerly Head, Strategic Sourcing, External Manufacturing, JOHNSON & JOHNSON CONSUMER HEALTHCARE

12:30 Lunch for Workshop Participants

3:40  Networking and Refreshment Break

4:10  PANEL DISCUSSION | From Guidance to Practice: A Look at Quality Agreements Across the Industry

- How are quality agreements being reviewed and assessed across the pipeline and multiple suppliers?
- What are the initial measures taken to update quality agreements in accordance with new guidance?
- How are you handling and managing pushback to new quality agreements from external manufacturers?
- What quantitative and qualitative metrics are in place to track the effectiveness of quality agreements?

Brian Clark, Executive Director, Quality, IMMUNOGEN, INC.
Nelson M Lugo, Senior Director, Contract Manufacturing, AMYLIN PHARMACEUTICALS, LLC (A Wholly Owned Subsidiary of BRISTOL-MYERS SQUIBB)
Wanda Tormos, Senior Manager, Chemical Development, Strategic Outsourcing, GILEAD SCIENCES, INC.

4:50  Are You Ready for a Pre-Approval Inspection? Comprehensive Strategies to Prepare for and Manage an FDA Inspection

- Demonstrate that you have control and oversight over product quality through robust quality controls and be consistently prepared for an unannounced inspection
- Follow ICH Q10 as a roadmap to develop an audit program, define and designate responsibilities and monitor and review performance of CMOs
- Gather and collect evidence to show you are managing outsourcing operations
- Know your inspector, have on-site support available, provide responses or commitments prior to submission

Prasad Gogineni, Director, Operations, ACTAVIS

To Register: Call 866-207-6528 | Visit www.exlpharma.com/CMO | Email registration@exlpharma.com
Day Two Thursday, April 24, 2014

8:00 Continental Breakfast for Conference Participants

9:00 Chairperson's Day Two Welcome and Day One Recap
Scott Duncan, Senior Staff Scientist, Chemical Development, ALKERMES

9:10 Conduct Thorough Risk Assessments of Suppliers to Manage Risk and Protect Your Supply Chain
Mike Gross, Senior GMP Compliance Auditor, BIOGEN IDEC

9:30 Align Quality Systems with External Manufacturers to Ensure High Quality
Dan Trimberger, Director, Quality Assurance, MOMENTA PHARMACEUTICALS

10:30 Morning Networking and Refreshment Break

11:00 SMALL MOLECULES PERSPECTIVE | Best Practice Models for Seamless Technology Transfer
James Nelson, Senior Director, Quality Assurance, ARENA PHARMACEUTICALS

11:40 BIOLOGICS PERSPECTIVE | Effective Strategies for Process Validation Quality Oversight
Lee Fox, Third Party Manufacturing Quality Manager, BRISTOL-MYERS SQUIBB

12:20 INTERACTIVE DISCUSSIONS | Quick Fire Exercises to Put Your Contract Manufacturing Problem Solving Skills to the Test
What issues would you like to solve? What situations have you experienced where the answer wasn’t obvious?
In this activity driven session attendees will break into teams and be presented with a range of common manufacturing conundrums to challenge attendees to think critically and react quickly to a range of common external manufacturing challenges. Teams will be diversified to represent a range of backgrounds and expertise to gain maximum best practices from a broad span of perspectives.
Is there an area or topic you would like covered? Email Marissa Alvord, the Conference Producer to ensure it will be included: malvord@exlpharma.com

Challenges to be explored could include:
• What do you do when you find out your CMO has been issued a 483?
• How will you implement operational excellence with external manufacturers without adversely impacting ongoing activities or the relationship?
• What do you do when your CMO isn’t delivering on schedule?
• You have failed to meet the specification for an intermediate during the third process validation run – what are your options?
• Your cGMP starting material from an external vendor managed by your CRO fails release due to foreign matter in the batch – how to proceed with manufacturing?
Scott Duncan, Senior Staff Scientist, Chemical Development, ALKERMES

1:00 Lunch

2:00 CASE STUDY | Establish a Meaningful Supplier Qualification/Partner Program
Jonathan Patroni, Head of North America Quality Assurance, Technical Operations, SHIRE

2:40 Afternoon Networking and Refreshment Break

3:00 CASE STUDY | Implement Contract Quality Requirements to Drive Continuous Improvement
Todd Mabe, Head of Biologics, Drug Substance, External Quality, PTQBX, ROCHE

3:40 CASE STUDY | Develop and Implement a Supplier Relationship Management Process to Drive Continuous Improvement
Madeline Fisher, Director, Supplier Quality Management, MEDIMMUNE - A DIVISION OF ASTRAZENECA

4:20 Conference Concludes
Sponsorship and Exhibit Opportunities

Do you want to spread the word about your organization's solutions and services to potential clients who will be attending this event? Take advantage of the opportunity to sponsor, underwrite an educational session, host a networking event, or distribute promotional items to attendees. ExL Pharma will work closely with you to customize a package that suits all your needs. To learn more about these opportunities, please contact Jeffrey Friedman at (917) 258-5163 or jfriedman@exlpharma.com

Five Ways to Register

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<td>494 8th Avenue, 4th floor</td>
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Group Discount Program

SAVE 25% per person when registering four
For every three simultaneous registrations from your company, you will receive a fourth complimentary registration to the program (must register four at one time). This is a savings of 25% per person.

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To find out more on how you can take advantage of these group discounts, please call 212-400-6240.
Please note that offers cannot be combined and group discount is off the standard registration rate.

Make checks payable to ExL Events, Inc. and write code C469 on your check. You may also use Visa, MasterCard, Discover or American Express. Payments must be received in full prior to the commencement of the conference.

Terms & Conditions

By registering for an ExL Events, Inc. ("ExL Pharma") event, you agree to the following set of terms and conditions listed below:

Registration Fee:
The fee includes the conference, all program materials, and designated continental breakfasts, lunches and refreshments.

Payment:
Must be received in full by the conference date. All discounts will be applied to the Conference Only fee (excluding add-ons), cannot be combined with any other offer, and must be paid at the time of order. Group discounts available to individuals must be registered simultaneously and employed by the same organization.

Cancellation and Refund Policy
If you need to cancel your registration for an upcoming ExL event, please note the following policies derived from the Start Date of the event:

- Four weeks or more: A full refund (minus a $295 processing fee) or a voucher to another ExL event valid for 18 months from the voucher issue date.
- Less than four weeks: A voucher to another ExL event valid for 18 months from the voucher issue date.
- If you cancel at any time after receiving the conference documentation, the voucher issued will be $395 less.

Substitution Charges:
There will be an administrative charge of $300 to substitute, exchange and/or replace attendee badges with a colleague occurring within five business days of the conference. ExL Pharma reserves the right to cancel any conference it deems necessary and will not be responsible for airfare, hotel or any other costs incurred by registrants. ExL Pharma’s liability is limited to the conference registration fee in the event of a cancellation and does not include changes in program date, content, speakers, or venue.

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Please Note: Speakers and agenda are subject to change without notice. In the event of a speaker cancellation, significant effort to find a suitable replacement will be made.

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Five Ways to Register

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☐ Yes!  Register me for the Conference Only

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Pre-Conference Workshop

Process Validation
Technology Transfer
Continuous Improvement
Quality System Alignment

Pre-Audit Opportunity Readiness
Quality Agreement Updates
Risk Assessment and Management
CMO Selection and Sourcing

Get equipped with a toolkit of robust quality oversight strategies for CMOs for stringent quality oversight.

Robust and Effective Auditing Procedures of CMOs for Stringent Quality Oversight

Thorough and rigorous auditing methods are a vital component of the quality oversight toolkit. Providers are consistently maintaining high quality standards.

To Register:
Call 866-207-6528 | Visit www.exlpharma.com/CMO | Email registration@exlpharma.com

April 23-24, 2014 Hyatt Regency Boston | Boston, MA
Maintaining Quality and Compliance with CMOs & Risk Management

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