A must attend GMP event for all pharmaceutical companies!

ADVANCED GMPS AND CURRENT REGULATORY ISSUES WITH FDA AND OTHER REGULATORY AUTHORITIES

11 – 13 JUNE 2019 | COPENHAGEN, DENMARK

REGISTER EARLY! SPECIAL DISCOUNTS AVAILABLE
Pharma Conference Education Inc returns to Copenhagen with an important and timely conference featuring an impressive roster of current and former regulatory personnel as speakers/presenters.

Headliners include Thomas Senderovitz, MD, Director General of the Danish Medicines Agency; Peter Marks, MD, PhD, Director of CBER, USFDA; Alonza Cruse, Director, Office of Pharmaceutical Quality Operations (OPQO), ORA, USFDA and many great industry speakers/presenters.

The conference will include eight workshops of one- and one-half hours which will repeat, allowing one attendee to attend four of the eight. To assure attendance of all workshops, bring at least two persons from your company. We are confident this conference will provide valuable and practical information to all pharmaceutical companies whose personnel attend.

The venue, Tivoli Hotel and Congress Center, is located a short walk from shopping areas and Central Station. Tivoli Gardens, Copenhagen's summer playground, is a short 25 minute walk from the hotel.

Pharma Conference is the same company that has produced GMP By The Sea in the US for 24 consecutive years, among other conferences (all are listed on our website).

Register now to take advantage of the early registration discount and to assure a place at this important conference with outstanding presenters and valuable information.

ABOUT THE CONFERENCE

WHO SHOULD ATTEND?

- Pharmaceutical persons involved with GMPs and Regulatory Matters, particularly FDA, EMA, Danish Medicines Agency, MHRA and Health Products Regulatory Authority

WHY ATTEND?

- To acquire important topical information from Regulatory Authorities
- To gain additional knowledge from industry presenters
- To keep current with the most recent changes and upgrades in GMPs

ABOUT THE VENUE

Said to be the world's most liveable city, Copenhagen strikes a balance between the old and the modern; between work and play; between simplicity and sophistication. Known around the world for its stunning architecture, outstanding cuisine, and famous sites such as Tivoli Gardens, The Little Mermaid sculpture, palaces, and shopping areas, Copenhagen has earned its place as a top tourist and business destination.

Register online at www.pharmaconference.com
John M. Hyde, BS, BBA, MS – Mr. Hyde is Chairman and Founder of Hyde Engineering + Consulting, Inc., a firm of 220+ engineers and scientists, founded in 1993 and specializing in process engineering, process and equipment validation, and compliance consulting for biopharmaceutical and pharmaceutical manufacturers. The company has operations in the United States, Europe, Singapore and India. For nearly two years prior to the formation of Hyde Engineering + Consulting, Inc., Mr. Hyde was Senior Project Engineer with Synergen, a biopharmaceutical research and manufacturing company. From 1982 to 1992, Mr. Hyde was Manager, Process Design with Seiberling Associates, Inc., an engineering firm specializing in the design and start-up of biopharmaceutical, food and beverage process systems and the application of CIP technology.

Henrik Friese, MSc – Mr. Friese, a pharmacist by education, is Corporate Vice President at Novo Nordisk A/S and has the responsibility for Quality intelligence and authority inspections at Novo Nordisk A/S. He has worked at Novo Nordisk for more than 23 years. Prior to his current role, he headed up several production sites at Novo Nordisk. Mr. Friese was Quality Vice President for a Production Site in Denmark and for many years was head of Manufacturing Development at Novo Nordisk, which included responsibility for establishment of new production sites in Brazil and China. In his current role Mr. Friese and his team are directly involved in all GMP inspections at Novo Nordisk and at the same time are responsible for capturing and securing implementation of new GMP regulations and trends.

Alonza Cruse, BS – Mr. Cruse is Director, Pharmaceutical Quality Program within the FDA Office of Regulatory Affairs. His office is responsible for all pharmaceutical inspections, working in conjunction with FDA’s Center for Drug Evaluation & Research and Center for Veterinary Medicine. From 2013-2015 Mr. Cruse served as the Director (Acting) of the Office of Medical Products & Tobacco Operations within ORA. From 2000-2015, Mr. Cruse was the Director, FDA’s Los Angeles District Office. Mr. Cruse first joined ORA in 1983 as a microbiologist.

Steve Greer, BS – Mr. Greer is the External Engagement Leader in Corporate QA for Procter & Gamble responsible for building collaborative relationships with boards of health and industry associations. At P&G, he has held leadership roles in manufacturing and quality assurance across the drug, cosmetic and home care sectors. He is co-chair of the Personal Care Products Council QA Committee and serves on the Quality Metrics Core Team of ISPE. Mr. Greer helps lead and is a popular speaker at numerous conferences on quality metrics, quality culture and improving human performance.

John M. Hyde, BS, BBA, MS – Mr. Hyde is Chairman and Founder of Hyde Engineering + Consulting, Inc., a firm of 220+ engineers and scientists, founded in 1993 and specializing in process engineering, process and equipment validation, and compliance consulting for biopharmaceutical and pharmaceutical manufacturers. The company has operations in the United States, Europe, Singapore and India. For nearly two years prior to the formation of Hyde Engineering + Consulting, Inc., Mr. Hyde was Senior Project Engineer with Synergen, a biopharmaceutical research and manufacturing company. From 1982 to 1992, Mr. Hyde was Manager, Process Design with Seiberling Associates, Inc., an engineering firm specializing in the design and start-up of biopharmaceutical, food and beverage process systems and the application of CIP technology.

Peter Marks, MD, PhD – Dr. Marks is Director, Center for Biologics Evaluation and Research, FDA. He received his graduate degree in cell and molecular biology and his medical degree at New York University and completed Internal Medicine residency and Hematology/Medical Oncology training at Brigham and Women’s Hospital in Boston. He has worked in academic settings teaching and caring for patients and in industry on drug development. He joined the FDA in 2012 as Deputy Center Director for CBER and became Center Director in January 2016.

Ginette Y. Michaud, MD – Dr. Ginette Michaud is a hematologist with 20 years of regulatory experience in biological products and medical devices. Since March of 2016, she has served as the Director of the Biologics Program in the FDA’s Office of Regulatory Affairs. Prior to joining ORA, Dr. Michaud was the Deputy Director, Office of Blood Research and Review in the Center for Biologics Evaluation and Research.
ABOUT THE SPEAKERS

Thomas Wejs Møller, MS – Mr. Møller is Section Manager – Medical Devices, Danish Medicines Agency, Denmark. He is an experienced manager in the public sector and has achieved good results with strategy, efficiency and management projects in the health care field. As section manager of medical devices in the DKMA, Mr. Møller works with the Danish health care sector, medtech industry, and Patient-NGOs to secure patient safety.

Søren Thuesen Pedersen, BSc (Chem) – Mr. Pedersen is a Chemical Engineer by education and has been with Novo Nordisk for 25 years. During that time he has led different areas within Manufacturing, QC-Laboratory, and CMC Manufacturing Development. He has been one of the founding fathers of the Novo Nordisk External Requirements’ Process. Mr. Pedersen is responsible for the External Representation of Novo Nordisk out of the GMP area and represents Novo Nordisk in ISPE, EFPIA, IFPMA and BIO. He has furthermore been a member of the Novo Nordisk Board of Directors for 12 years as an elected employee representative.

Ulrich Pflugmacher, PhD – Dr. Pflugmacher has more than 20 years experience in the Pharmaceutical Industry. After starting as a lab head in QC Microbiology of Hoechst Marion Roussel, he worked as a Sterility Assurance Manager for different aseptic products. Later, he became head of QC Microbiology at Aventis/Sanofi-Aventis Deutschland and was also acting Site Quality Manager of a large injectable site. Currently, he is Director for Sterile Technologies in the Global Quality Network of the Injectable Sites of Sanofi. This position includes a global quality responsibility for RAB systems.

Siegfried Schmitt, PhD – Dr. Schmitt joined PAREXEL Consulting in 2007. He provides consulting services to the healthcare industry on all aspects of regulatory compliance, particularly the design and implementation of agile Quality Management Systems. He has previously held positions in industry with Roche, GE Healthcare, Raytheon and ABB. He is a regular conference presenter and accomplished author and editor.

Thomas Senderovitz, MD – Dr. Senderovitz is Director General of the Danish Medicines Agency, Chair of the Heads of Medicines Agencies Management Group and a member of EMAs Management Board. He is a member of the EU Telematics Management Board, a member of the Steering Committee of the Center for Regulatory Science, University of Copenhagen, a member of the Reference Group for the Center of Public Leadership, University of Aarhus, and a member of the Board of the Danish Strategy for Personalized Medicine. He is an MD from the Faculty of Medicine, University of Copenhagen with more than 26 years of experience in healthcare, the pharmaceutical industry, biotech, CRO, and regulatory authorities. Dr. Senderovitz has held several senior management positions within R&D in PAREXEL International, GlaxoSmithKline, UCB and Ferring and has founded two biotech companies.

Peter D. Smith, BS – Mr. Smith, Principal, Smith GMP Consulting, began an independent consulting company upon retiring from PAREXEL in April 2018 after 23+ years. He continues to work with clients in the pharmaceutical and biologics industry worldwide. Mr. Smith joined PAREXEL (then KMI) in 1994 following a 22-year FDA career. He held various positions with PAREXEL, with his final position as Vice-President Technical in the Strategic Compliance group. At the FDA, Mr. Smith worked as an Investigator, specializing in pharmaceutical GMP/GCP and medical device inspections in the field and later serving as Associate Director, International and Technical Operations Branch, Division of Field Investigations at FDA headquarters in Rockville, MD, where he managed the Foreign Inspection Program. During his FDA career, he conducted inspections of pharmaceutical plants in Europe, Asia, South America and Australia. He is a highly experienced public speaker and trainer in GMP and FDA inspection readiness topics.

Veda Walcott, MT, BS, MBA – Ms. Walcott is Vice President of Regulatory Affairs and Compliance for Catalent Pharma Solutions where she is responsible for corporate regulatory affairs policy and compliance and contract development and manufacturing organization regulatory affairs support for a broad product portfolio. She most recently served as Vice President of Quality and Regulatory Affairs for Catalent Indiana, LLC (formerly Cook Pharmica) from 2007 to 2018 and was responsible for oversight of the quality management system, validation and regulatory affairs for the Bloomington, Indiana mammalian cell culture and parenteral filling, inspection, and packaging CDMO. Prior to starting her career in the pharmaceutical industry, Ms. Walcott was employed as a Medical Technologist at IU Health Bloomington Hospital.

Jan B. Welch, BS, MHS – Ms. Welch serves as Director, Office of Medical Device and Radiological Health Operations, within the Office of Regulatory Affairs (ORA), Food and Drug Administration (FDA). She leads organizational change to a commodity-based program emphasizing specialization and vertical integration of regulatory processes. Ms. Welch previously led the Office of Compliance in FDA’s Center for Devices and Radiological Health, overseeing the assessment and enhancement of medical device quality through broad-based FDA change initiatives and daily operations. She was also a quality system expert, providing expert opinion on medical device legal cases, developing and presenting extensive training on the quality system regulations, and representing FDA and the U.S. in several international guidance and standards activities. Previously Ms. Welch worked at the Office of Compliance in the Center for Biologics Evaluation and Research. Before joining FDA, she worked for the American Red Cross, the National Institutes of Health, and Vanderbilt University Medical Center.
AGENDA

Tuesday, 11 June, 2019

Morning Session: Moderator – David Chesney

7:30 – 8:30  Registration
8:30 – 8:40  Welcome
8:40 – 9:25  Keynote: Status of MRA and Progress and Areas of Interest in Europe  
             Thomas Senderovitz, MD, Danish Medicines Agency
9:25 – 10:10  Leadership Keys to Improving Human Performance  
              Steve Greer
10:10 – 10:30  Break*
10:30 – 11:15  CBER – FDA Update  
               Peter Marks, MD, PhD, USFDA, CBER
11:15 – 12:00  Essential FDA Information, i.e., Inspections and Other FDA Issues  
               Alonza Cruse, USFDA, ORA, OPQO — invited
12:00 – 12:30  Question and Answer Session
12:30 – 1:45  Lunch*

Afternoon Session: Workshops

1:45 – 3:15  Workshop 1: Contract Manufacturing – CMO and Big Pharma View Points  
              CMO – Veda Walcott
              Big Pharma – To Be Determined
2:00 – 3:15  Workshop 2: Leadership Keys to Success to Improve Human Performance  
              Steve Greer
              John Hyde
              David Chesney
3:35 – 5:05  Workshop 4: Structure for Deploying New Regulatory Requirements Companywide  
              Henrik Friese
              Søren Thuesen Pedersen
3:15 – 3:35  Break*
3:35 – 5:05  Workshops Repeated
The above workshops will be repeated (except Workshop 3, which will be a continuation of the earlier session)

5:30 – 7:30  Networking Reception*

Workshop 3: Quality and Compliance Management for Virtual Companies – Part II  
              David Chesney

Wednesday, 12 June, 2019

Morning Session: Moderator – Gary Bird, PhD

8:30 – 9:10  Inspection Impact for Products Transitioning from CDER FDA to CBER FDA  
             Alonza Cruse, USFDA, ORA, OPQO — invited
9:10 – 9:50  Contemporary Approaches to Cleaning Validation in a World of Pharma Mergers and Acquisitions  
             John Hyde
9:50 – 10:30  CDER – FDA Update  
              CDER Representative, USFDA — invited
10:30 – 10:50  Break*
10:50 – 11:30  Quality Metrics – The Journey to Value  
                Steve Greer
11:30 – 12:15  Current Regulatory Matters on Medical Devices, Including MDSAP  
                Thomas Wejs Møller, Danish Medicines Agency
12:15 – 12:30  Question and Answer Session
12:30 – 1:45  Lunch*
### Afternoon Session: Workshops

<table>
<thead>
<tr>
<th>Time</th>
<th>Workshop</th>
<th>Presenter</th>
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<tbody>
<tr>
<td>1:45 – 3:15</td>
<td><strong>Workshop 1: Quality Metrics</strong></td>
<td>Steve Greer</td>
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<td><strong>Workshop 2: Case Studies in Transition to Restricted Access Barrier Systems (RABS) and Implementation of Changes to Annex I</strong></td>
<td>Ulrich Pflugmacher, PhD</td>
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<td><strong>Workshop 3: Quality and Compliance Management for Virtual Companies – Part I</strong></td>
<td>David Chesney</td>
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<td><strong>Workshop 4: Update on Annex 1</strong></td>
<td>Siegfried Schmitt, PhD</td>
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<td>3:15 – 3:35</td>
<td>Break*</td>
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<td>3:35 – 5:05</td>
<td><strong>Workshops Repeated</strong></td>
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<td><strong>Workshop 3: Quality and Compliance Management for Virtual Companies – Part II</strong></td>
<td>David Chesney</td>
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#### Thursday, 13 June, 2019

### Morning Session: Moderator – Peter Smith

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<tr>
<th>Time</th>
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<tr>
<td>8:30 – 9:10</td>
<td><strong>Review of FDA’s Current Biologic Issues</strong></td>
<td>Ginette Michaud, MD, USFDA, ORA, OBPO – invited</td>
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<td>9:10 – 9:50</td>
<td><strong>Revised Annex 1</strong></td>
<td>Brendan Cuddy, EMA – invited</td>
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<td>9:50 – 10:30</td>
<td><strong>Deviation and OOS Investigations and Reports – Part 1</strong></td>
<td>Peter Smith</td>
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<td>10:30 – 10:50</td>
<td>Break*</td>
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<tr>
<td>10:50 – 11:30</td>
<td><strong>Deviation and OOS Investigations and Reports – Part 2</strong></td>
<td>Peter Smith</td>
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<tr>
<td>11:30 – 12:10</td>
<td><strong>Supply Chain – Good Supply Practices – Practical Solutions You Can Implement to Strengthen Your Supply Chain</strong></td>
<td>To be determined</td>
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<tr>
<td>12:10 – 12:30</td>
<td><strong>Question and Answer Session</strong></td>
<td>Morning Speakers</td>
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<td>12:30 – 1:45</td>
<td>Lunch*</td>
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### Afternoon Session: Moderator – John Hyde

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<tr>
<td>1:45 – 2:30</td>
<td><strong>Quality Culture – Lessons Learned in Avoiding a Consent Decree</strong></td>
<td>Steve Greer</td>
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<tr>
<td>2:30 – 3:15</td>
<td><strong>Review of FDA’s Current Medical Device Issues</strong></td>
<td>Jan Welch, USFDA, ORA, OMDRHO – invited</td>
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<td>3:15 – 3:35</td>
<td>Break*</td>
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<td>3:35 – 4:10</td>
<td><strong>Question and Answer Session</strong></td>
<td>Afternoon Speakers</td>
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*Denotes non-educational activity

Pharma Conference Education Inc reserves the right to make changes to the conference agenda

**Continuing Education:** This conference qualifies for 18.0 hours of continuing education credit.

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Fees

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Includes conference materials, breaks, lunches, and evening events per agenda (breakfast included with hotel room rate)

Cancellation Policy: 30 days or more for a full refund less $250 USD cancellation fee; under 30 days, no refund, but attendee substitutions may be made at any time. Cancellations and substitutions must be made in writing to Pharma Conference Education Inc (email registration@pharmaconference.com). In the event of any civil disorder, extremely adverse weather conditions, or other Acts of God, Pharma Conference Education Inc reserves the right to reschedule the meeting dates in the interest of attendee safety.

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For additional information, contact Pharma Conference Education Inc: 830-315-0055 • e-mail: contactus@pharmaconference.com

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