2018 PDA Annual Meeting 2018年PDA年会

Agile Manufacturing Strategies: Driving Change to Meet Evolving Needs

敏捷制造策略：推动变革以满足不断变化的需求

March 19-21, 2018 | Loews Sapphire Falls | Orlando, FL

2018年3月19日-21日|美国弗罗里达州奥兰多市 |

环球洛伊斯蓝宝石瀑布度假村

As of December 21, 2017

2017年12月21日

Sunday, March 18 3月18日，星期日

1:00 p.m. – 7:00 p.m.
Exhibitor Set Up 布置展位

4:00 p.m. - 7:00 p.m.
Registration Open 注册

4:00 p.m. - 7:00 p.m.
Speaker Ready Room Open演讲者准备室开放

6:30 p.m. - 9:30 p.m.
PDA Awards Dinner *(Invitation Only)* **PDA颁奖晚宴**（仅限邀请）

Monday, March 19 3月19日，星期一

7:00 a.m. – 4:00 p.m.
Exhibitor Set Up 布置展位

9:00 a.m. - 5:00 p.m.
Registration Open 注册

9:00 a.m. - 5:00 p.m.
Speaker Ready Room Open 演讲者准备室开放

12:00 p.m. - 1:00 p.m.
Refreshments Available 茶歇

1:00 p.m. - 1:30 p.m.
Welcome and Opening Remarks from the Chair of the PDA Board of Directors, PDA's President and, the Meeting Program Planning Committee Co-Chairs
PDA理事会主席、PDA总裁以及会议议程筹备委员会联合主席致欢迎和开幕辞
Rebecca Devine, Biopharmaceutical Consultant
Richard Johnson, President and CEO, *PDA*
Ghada Haddad, MBA, Executive Director, Global GMP Auditing, *Merck & Company*
Morten Munk, Global Technology Partner, *NNE*

Rebecca Devine，生物制药顾问
Richard Johnson，PDA总裁兼首席执行官
Ghada Haddad，MBA，默克公司全球GMP审计执行总监
Morten Munk，NNE全球技术合作伙伴

1:30 p.m. - 3:00 p.m.
P1: Patient Perspective - Future Visions
P1：患者视角——未来愿景
Moderator: Morten Munk, Global Technology Partner, *NNE*
主持人：Morten Munk，NNE全球技术合作伙伴

Session Description: All delegates at this conference are in some way involved in the path of providing pharmaceuticals to patients. It is a privilege and offers a clear purpose to be part of a community that have the possibility to make an instrumental difference to the individual patient as well as to the society in general. This option to make a difference, comes with substantial responsibility to ensure that we do our outmost to meet the expectations of the patients and health care

professionals, who rely on us in providing safe and effective pharmaceuticals. During a busy workday with numerous daily challenges, the outcome of our work might be a bit out of focus, and maybe not the first thing we think about when we start working in the morning. This session offers to give a clear perspective of the individuals that ultimately are benefiting from our daily efforts.
描述：参加本次大会的所有代表都以某种方式参与了向患者提供药品的行动。作为一个可能对患者以及整个社会带来重大影响的团体，这是一种特权，同时也提供了明确的目标。我们肩负着重大责任，患者和医疗专业人员需要我们提供安全有效的药品，我们将通过变革确保尽最大努力来达到他们的期望。在每天的繁忙工作中，我们都要面对无数挑战，我们的工作成果可能会并未得到如此重视，也可能并非我们每日最先的考量。这部分从最终受益于我们日常工作的个人角度展开研讨。

1:30 p.m. - 2:00 p.m.

Clinician Perspective on Future Patient Therapies
未来患者治疗的临床医生视角
Stephen Kingsmore, MD, President and CEO, *Rady Children's Institute for Genomic Medicine* **医学博士，*Rady儿童基因组医学研究所*总裁兼首席执行官**

2:00 p.m. - 2:30 p.m.

Patient Perspective
患者视角
Lori Richter, Senior Consultant, *ValSource LLC*
Lori Richter，*ValSource有限责任公司*高级顾问

2:30 p.m. - 3:00 p.m.

Questions and Answers/Discussion
问答/讨论

3:00 p.m. -3:30 p.m.
Refreshment Break 茶歇

3:30 p.m. - 5:00 p.m.
P2: Disruptive Technology and the Future of Medicine
P2：颠覆性技术和医学的未来
Moderator: Tia Bush, Vice President, Quality, *Amgen, Inc.*
主持人：Tia Bush，安进公司质量副总裁

Session Description: Today's healthcare is not sustainable due to the rising costs of treatment, ageing populations, and healthcare worker shortages. The future of medicine will be innovative, patient focused, and digital. Our industry and the regulatory framework that governs our products and services must overcome technical and cultural challenges by embracing disruptive technologies that make healthcare more effective, by putting patients in the center of healthcare strategies, by digitizing information to grow our understanding of disease and treatment, and shifting the healthcare from a "break and fix" mentality to one of prevention. This session will explore the trends in technology and how they will alter our current view of the healthcare system and the medicines we make to improve the lives of patients. We will also explore how companies must build their culture of innovation in order to deliver on this promise.
描述：由于治疗费用的提高、人口老龄化和医护人员短缺，目前的医疗并不具有可持续性。未来的医学将是创新、以患者为中心和数字化的。我们行业以及监管我们产品和服务的法规框架必须应对技术和文化挑战，应采取使医疗变得更有效的颠覆性技术、将患者作为医疗策略的中心、通过信息数字化来提高我们对疾病和治疗的理解，将医疗从"打破和修复"的心态向预防转移。这部分将探讨技术的趋势，以及它们将如何改变我们对医疗系统和用于改善患者生活的药品的现有看法。我们还将探讨各家公司如何建立自己的创新文化，以履行这一承诺。

3:30 p.m. - 4:00 p.m.
Company Dynamics
公司动态
Steven Spear, PhD, Senior Lecturer, System Dynamics, *Massachusetts Institute of Technology (MIT)*
Steven Spear，博士，麻省理工学院（MIT）系统动力学高级讲师

4:00 p.m. - 4:30 p.m.
Regulatory Perspective on New Technologies
Regulatory Representative Invited
对新技术的监管视角
已邀监管机构代表

4:30 p.m. - 5:00 p.m.
Questions and Answers/ Discussion
问答/讨论

5:00 p.m. - 6:30 p.m.
Grand Opening Celebration in Exhibit Hall
在展示厅举行盛大开幕庆典

Tuesday, March 20 3月20日，星期二

7:30 a.m. - 5:30 p.m.
Registration Open 注册

7:30 a.m. - 5:30 p.m.
Speaker Ready Room Open 演讲者准备室开放

7:30 a.m. -8:30 a.m.
Continental Breakfast 欧式早餐

8:30 a.m. - 10:00 a.m.
P3: Genomic Profiling
P3：基因组分析
Moderator: Austin Caudle, MSc, Associate Director, Business Development, *IQVIA*
主持人：Austin Caudle，理科硕士，*IQVIA*业务发展副总监

Session Description: Our understanding of genomics is dramatically changing healthcare, leading the way to personalized care. Advances in the field of DNA sequencing and the ability to collect and analyze large amounts of data quickly has played a critical role in the evaluation of research. Using genomic profiling it is possible to map an individual's unique genomic profile, providing physicians with invaluable information to help determine the best treatment. It can be used to find out why certain people get diseases while others do not, or why people react differently to the same drug. Likewise, this data can help biotech companies make informed decisions in their R&D investments. This session will explore the role of genomic profiling as a tool for identifying the potential risk of certain health conditions and application of treatment strategies/therapies that are tailored to the genetic profile of each patient.
描述：我们对基因组学的理解正在对医疗带来显著改变，并且开始向个性化治疗方式发展。DNA测序领域的进展以及快速收集和分析大量数据的能力在研究评估中发挥了关键作用。通过使用基因组分析，可以绘制出个人独特的基因档案，为帮助医生确定最佳治疗方案提供宝贵的信息。可以用来发现为什么某些人会患上某些疾病，而其他人不会，或者为什么人们对同一种药物会产生不同的反应。同样，这些数据可以帮助生物技术公司在研发投资中做出明智决定。这部分将探讨把基因组分析作为一种工具，用它来确定某些健康状况的潜在风险以及根据每个患者的基因档案采用定制的治疗策略/治疗方法。

8:30 a.m. - 9:00 a.m.
Learning from Kymriah, a CAR-T Therapy Which Targets B Cell Malignancies
Kymriah的研究发现，一种针对B细胞恶性肿瘤的CAR-T治疗方法
David Lebwohl, MD, Franchise Global Program Head, CAR-T Team, *Novartis Pharmaceuticals Corporation*
David Lebwohl，医学博士，诺华制药有限公司CAR-T团队特许全球项目负责人

9:00 a.m. - 9:30 a.m.
Industry Perspective on Genomic Profiling
对基因组分析的行业视角
Industry Presenter Invited
已邀行业演讲嘉宾

9:30 a.m. - 10:00 a.m.
Questions and Answers/Discussion
问答/讨论

9:45 a.m. - 6:30 p.m.
Exhibit Hall Open
展示厅开放

10:00 a.m. - 10:45 a.m.
Refreshment Break and Poster Presentations in Exhibit Hall
茶歇和展示厅海报展示

10:45 a.m. - 12:15 p.m.
Concurrent Sessions 并行会议

Track: Innovative Manufacturing Strategies **分论坛：创新制造策略**	**Track: Handling Complexity in the Product Value Chain** **分论坛：处理产品价值链中的复杂性**	**Interest Group** **兴趣小组**	**Interest Group** **兴趣小组**
A1: IT: So Much More than Technology **A1：IT：不仅是技术** **Moderator:** **Aaron Goerke, PhD,** Associate Director/Head of Global Engagement and Deployment, *F. Hoffmann-La Roche Ltd.* 主持人：Aaron Goerke，博士，罗氏制药有限公司副总监/全球参与及部署负责人	**B1: In-House vs. CMO** **B1：内部 vs.CMO** **Moderator:** **Marcia C. Baroni,** Director, QC Microbiology & EM/Sterility Assurance, *Eli Lilly and Company* 主持人：Marcia C. Baroni，礼来公司QC微生物学和EM/无菌保证总监	**IG1: Process Validation** **Leader: Scott Bozzone, PhD,** Principal, *Pharm Lifecycle Validation, LLC* IG1：工艺验证 组长：Scott Bozzone，博士，Pharm Lifecycle Validation公司负责人	**IG2: Filtration** **Leader: Maik W. Jornitz, MS** CEO, *G-Con Manufacturing* IG2：过滤 组长：Maik W. Jornitz，理学硕士，G-Con Manufacturing公司首席执行官
Session Description: The IT revolution is evident all around us, but the emphasis has mostly been on the T, the technology. It is time to recast our gaze to focus on the I, the information. Perhaps this information really means insight. Has your company made this transition and began treating data as an asset and not a cost? Are you getting insight out of information? Responses vary across Pharma manufacturing as do their ability to harness information in novel ways to produce insights of significant value. This session will explore examples of where data is being put to new uses to solve difficult real-world problems. Different strategies, learning's and challenges encountered, some of which might not have been overcome, will be key takeaways. There is a revolution underway in IT, but it is just as much in the information side of the acronym as in technology. 描述：IT革命在我们周围随处可见，但关注的重点主要在于T（技术），现在	**Session Description:** The face of pharmaceutical manufacturing has changed drastically in the past two decades. Not only from a technological and science standpoint, but also with regards to the regulatory and political environment. Shorter patent protection, lower price premiums and increasing barriers to reimbursability have created a market where faster development, smaller volumes and increasing levels of customization are not only more common, but also more desirable. Deciding when to invest in house and when to leverage a third party has become a critical business decision, as limited resources must be carefully divided amongst a wider range of needs. Third party companies are being actively leveraged cross all stages of the product lifecycle, from development to launch and through product end of life; from the labs to manufacturing. This session will explore a few of those scenarios, sharing experiences and points to consider when making these critical decisions.	**Session Description:** This session will have short presentations on current issues in process validation (PV), followed with open discussion afterwards. A small panel of SMEs will be assembled to lead the open discussions. 描述：这部分将对当前工艺验证（PV）中的问题进行简短介绍，随后进行公开讨论。 将由小组专家来主持公开讨论。	**Session Description:** Annex I includes a controversial paragraph on the integrity test pre-use/post sterilization. This paragraph causes severe problems within the industry. Since the Annex I revision will be published, we require to review the paragraph posted in the revised Annex I and see what activities require to be taken. 描述：附件一包含一个关于使用前/后灭菌完整性测试的争议性段落。这个段落在行业里引起了严重问题。由于将要发布附件一的修订版本，我们要对修订后的附件一中发布的段落进行审查，看看需要采取哪些行动。 We will also inform about new initiatives regarding PUPSIT: 我们还将告知关于PUPSIT的新计划： • Statement by filter manufacturers • Blocking test proposal within PDA TRI • MOU with BPOG to work together on PUPSIT • 过滤制造商的声明

我们应当将关注点转为I（信息），信息可能真的意味着见解。你的公司是否已经进行了这一变革，开始将数据视为资产而不是成本？你是否已从信息中得到见解？各个制药公司的反应各不相同，因为在以创新方式利用信息产生具有重要价值的见解方面，他们的能力也有所不同。这部分探讨将数据投入新应用以解决实际难题的例子。不同的策略、知识以及遇到的挑战都将会成为关键信息，虽然其中一些可能尚未克服。IT正在经历一场革命，信息与技术将会占据同等比重。	描述：在过去二十年里，制药行业发生了翻天覆地的变化。不仅从技术和科学角度方面有所变化，并且还涉及监管和政治环境。更短专利保护期、更低价格、及提高的报销门槛催生了一个市场，更快研发、更小容量和更高定制化水平将更常见，且更受欢迎。 决定何时进行内部投资以及何时利用第三方已经成为一项关键的商业决策，因为必须在更广泛的需求范围内小心地分配有限资源。目前，在产品生命周期的所有阶段都积极地利用了第三方公司，从开发到上市，一直到产品生命周期的结束；从实验室到制造。这部分将对其中一些方面进行探讨，分享做出这些关键决策的经验和考虑重点。		• PDA TRI中的封闭试验建议 • 与BPOG针对PUPSIT共同开展工作的备忘录

10:45 a.m. -11:15 a.m. **Insights on the Manufacturing Floor** **对制造车间的见解** **Michele D'Alessandro,** Vice President and Chief Information Officer, Manufacturing IT, *Merck & Co./Merck Sharp & Dohme* **Michele D'Alessandro，默克公司/默沙东制造IT副总裁兼首席信息官** 11:15 a.m. -11:45 a.m. **Beyond the Product – Data, Insights, and Value** **产品之外——数据、见解和价值** **Thomas Seewoester, PhD,** Executive Director and Plant Manager, *Amgen Inc.* **Thomas Seewoester，博士，安进公司执行总监和工厂经理** 11:45 a.m. -12:15 p.m. **Questions and Answers/Discussion** **问答/讨论**	10:45 a.m. -11:15 a.m. **Strategies and Complexities around Outsourcing of Labs** **实验室外包的策略和复杂性** **Jeffrey T. Gelwicks, PhD,** Senior Director, Global Quality Labs, *Eli Lilly and Company* **Jeffrey T. Gelwicks，博士，礼来公司全球质量实验室高级总监** 11:15 a.m. -11:45 a.m. **Contract Manufacturing/Supply Chain** **合同制造/供应链** **Dennis Kim,** Vice President, Operations, Global Manufacturing and Supply Chain, *Takeda Pharmaceuticals* **Dennis Kim，武田制药全球制造和供应链运营副总裁** 11:45 a.m. -12:15 p.m. **Questions and Answers/Discussion** **问答/讨论**		

12:15 p.m. -1:45 p.m.
Networking Luncheon in Exhibit Hall
展示厅交流午宴

1:45 p.m. -3:15 p.m.
Concurrent Sessions
并行会议

Track: Innovative Manufacturing Strategies **分论坛：创新制造策略**	**Track: Disruptive Technologies** **分论坛：颠覆性技术**	**Interest Group** **兴趣小组**	**Interest Group** **兴趣小组**
A2: Control Strategies for Continuous Processing **A2：连续工艺的控制策略** **Moderator:** **Melissa Seymour,** Vice President, Corporate Quality, *Biogen* 主持人：Melissa Seymour，百建公司企业质量副总裁	**B2: Aseptic Processing/Isolators** **B2：无菌工艺/隔离器** **Moderator: Shelley Preslar, MBA, PMP,** General Manager, *Azzur Group* 主持人：Shelley Preslar，MBA，PMP，Azzur集团总经理	**IG3: Quality Risk Management** **IG3：质量风险管理** **Leaders: Amanda Bishop McFarland, MS,** Consultant**,** *ValSource, LLC* and **Emma Ramnarine**, Head, Global Biologics Quality Control, *Genentech, A Member of the Roche Group* 组长：Amanda Bishop McFarland，MS，ValSource公司顾问和Emma Ramnarine，罗氏集团旗下基因泰克公司全球生物制剂质量控制负责人	**IG4: Biopharmaceutical Manufacturing** **IG4：生物制药** **Leaders: Arleen C. Paulino,** Vice President, Singapore Site Operations, *Amgen Inc.* and **Peter Makowenskyj,** Sales Engineer, *G-CON Manufacturing, Inc.* 组长：Arleen C. Paulino，安进公司新加坡现场运营副总裁和Peter Makowenskyj，G-CON Manufacturing公司销售工程师

Session Description: Continuous manufacturing offers compelling benefits with respect to costs, process flexibility and capacity. In fact, the 21st Century Cures Act, enacted in December 2016, authorized grants to support studying Continuous Manufacturing of drugs and biological products. Control strategies for these processes must also continuously provided assurance of quality, mitigating any risk to product quality because of process variations over time. This session will focus on science and risk based approaches to control strategies that can be implemented to monitor and ensure appropriate	**Session Description:** The need for improved aseptic manufacturing capabilities has led to innovations in Isolator technology. To meet increasing product demand while ensuring patient safety and product quality requires new thinking in implementing aseptic processes and capabilities. To continue to be effective manufacturing it is necessary to look at systems that are reliable yet flexible. This session will showcase two different strategies for implementation of strategies to improve aseptic processing capabilities. Speakers will share innovative ways to	**Session Description:** Surviving a QRM Program Audit: With new and evolving manufacturing strategies, QRM programs are also evolving to meet new demands and in some cases becoming more mature. With this change in the environment, Regulatory Authorities are also changing and requiring more from the industry with respect to their QRM programs. In this session we will discuss strategies in presenting a QRM program to Health Authorities, with	**Session Description:** BioAB has recently changed the name and scope for the Biotechnology IG. We renamed the IG to Biopharmaceutical Manufacturing as this focus better aligns with PDA's overall mission to advance pharmaceutical manufacturing science and technology. This session represents the inaugural meeting for the newly formatted Biopharmaceutical Manufacturing IG. The session program includes: • Outline the objective and mission of the

understanding of process dynamics and their relation to process conditions and raw material control. Tools including model-based control, multivariate monitoring, automation and real-time release testing will be discussed as well as identification and rejections of non-conforming segments. 会议描述：连续制造为成本、工艺灵活性和容量带来了显著优势。事实上，在2016年12月颁布的“21世纪治愈法案”中，授权准许支持研究药品和生物制品的连续制造。此外，还必须持续对这些工艺提供控制策略，以确保质量，减少由于工艺变化造成的产品质量风险。这个部分将重点针对基于科学和风险的方法，通过控制可执行策略来监控和确保对工艺动态以及它们与工艺条件和原料控制的关系的适当理解。对包括基于模型的控制、多变量监测、自动化和实时发布测试在内的工具将进行讨论，并识别和拒绝不合格部分。	implement robotics and environmental considerations with regards to isolator technology. 会议描述：对改进无菌制造能力的需求带来了隔离器技术创新。为了满足不断增长的产品需求并确保患者安全和产品质量，需要在实施无菌工艺和能力方面采用新的思维方式。为了继续确保有效制造，必须寻找可靠灵活的系统。这个部分将展示为了提高无菌工艺能力采用的两种不同策略。 演讲者将分享使用机器人的创新方式，以及对隔离器技术在环境方面的考虑。	presenters who will provide actual examples and case studies. Participants will also be working in teams to develop audit strategies and responses to practice scenarios. Examples will be presented that address both what the auditor is expecting as well as how the auditee should plan on responding. This will include both proper and improper use of QRM in audit responses. The session will end with lively dialogue involving both the participants and the presenters, as we work through the scenarios as a group. 会议描述：通过质量风险管理（QRM）计划审计：通过采用新的和不断发展的制造策略，QRM计划正在不断变化，以满足新的需求，在某些情况下变得更加成熟。由于环境变化，监管机构也在不断变化并且需要行业对他们的QRM项目提供更多支持。在这个部分中，我们将讨论向卫生主管部门提交QRM计划的策略，演讲者将提供具体例子和案例研究。参与者将与团队合作制订审计策略以及对实际情况的响应。讲述的例子将针对审计方预期的方面以及被审计方应当计划如何响应。包括在审计响应中QRM的正确和错误使用。在这个部分的最后，将安排一组由参与者和演讲者共同参与的生动对话，我们将作为一个团队一起了解各种情况。	Biopharmaceutical Manufacturing IG • Solicit input from participants on future directions and focus areas for the IG Following this introductory discussion, the session will focus on the latest developments in manufacturing science and technology for biopharmaceutical products including advanced cell and gene therapies. The content will include both presentation and time for interactive dialogue addressing topics related to process optimization to streamline operations, improvements to increase efficiency and reduce costs, and approaches for achieving the highest level of biopharmaceutical product quality. 会议描述：BioAB最近改变了生物技术IG的名称和范围。我们将IG重新命名为生物制药，因为这个重点更符合PDA推动制药科学和技术的整体使命。这个部分代表了新形式的生物制药IG的开幕会议。 会议议程包括： •概述生物制药IG目标和任务 •关于IG的未来方向和重点领域向参与者征求意见 在这个介绍性讨论之后，会议将重点针对生物制药产品的制造科学和技术的最新发展，包括先进细胞和基因疗法。内容将包括演讲和互动对话时间，主要针对通过工艺优化简化操作、提高效率和降低成本，以及达到生物制药产品最高质量的方法。

1:45 p.m. -2:15 p.m. **Continuous Manufacturing: Considerations on Controls of a Dynamic Process** **连续制造：对动态工艺控制的思考** **Markus Krumme, PhD,** Head, Continuous Manufacturing Unit, *Novartis* **Markus Krumme，博士，诺华连续制造单元负责人** 2:15 p.m. -2:45 p.m. **Building Quality in Continuous API Manufacturing: Key Learnings** **在连续API制造中建立质量：关键知识** **Erwin Irdam,** Principal Engineer, Technical Development, *Biogen* **Erwin Irdam，百健公司技术开发首席工程师** 2:45 p.m. -3:15 p.m. **Questions and Answers/Discussion** **问答/讨论**	1:45 p.m. -2:15 p.m. **Installation and Qualification of a Closed, Gloveless Isolator System for Aseptic Filling** **无菌灌装封闭式无手套隔离器系统的安装和认证** **Terrence E. Hollis,** Process Engineering Manager, *Patheon* **Terrence E. Hollis，** *Patheon*工艺工程经理 2:15 p.m. -2:45 p.m. **Can RABS and Isolator Cleanroom Technology be Combined to Help Achieve the Highest Level of Quality and Flexibility in Aseptic Processing? A New Approach allows Companies to Take Advantage of Both Cleanroom Technologies** **RABS和隔离器洁净室技术是否可以结合在一起帮助达到无菌处理的最高质量水平和灵活性？一种帮助各家公司利用两种洁净室技术的新方法** **Ute Schleyer, PhD,** Project Manager, Plant and Site Development, *Vetter Pharma-Fertigung GmbH & Company KG* **Ute Schleyer，博士，** *Vetter Pharma-Fertigung GmbH & Company KG*工厂和现场开发项目经理 2:45 p.m. -3:15 p.m. **Questions and Answers/Discussion** **问答/讨论**	**Speakers:** **演讲者：** **Ghada Haddad, MBA,** Executive Director, Global GMP Auditing, *Merck & Company, Merck Sharpe & Dohme* **Ghada Haddad，MBA，默克公司/默沙东全球GMP审计执行总监** **Lori Richter,** Senior Consultant, *ValSource LLC* **Lori Richter，ValSource公司高级顾问**	**Speakers:** **演讲者：** **Scale Out vs Scale Up for Biologics Manufacturing** **生物制剂制造的横向扩展vs纵向扩展** **Weichang Zhou, PhD,** Chief Technology Officer, Senior Vice President, Biologics Development and Manufacturing, *WuXi Biologics* **Weichang Zhou，博士，药明生物生物制剂开发和制造首席技术官兼高级副总裁** **Peter Makowenskyj,** Sales Engineer, *G-CON Manufacturing, Inc.* Peter Makowenskyj，G-CON Manufacturing公司销售工程师

3:15 p.m. -4:00 p.m.
Refreshment Break and Poster Presentations in Exhibit Hall
茶点休息时间和展示厅海报展示

4:00 p.m. -5:30 p.m.

Concurrent Sessions 并行会议

Track: Innovative Manufacturing Strategies **分论坛：创新制造策略**	**Track: Disruptive Technologies** **分论坛：颠覆性技术**	**Interest Group** **兴趣小组**	**Interest Group** **兴趣小组**
A3: Agile Bioprocessing **A3:敏捷生物工艺** **Moderator:** **Michael De Felippis, PhD,** Senior Research Fellow, Bioproduct Research & Development, *Eli Lilly and Company* **主持人：** **Michael De Felippis，博士，礼来公司生物制品研发高级研究员**	**B3: Trends in Digital Information and Automated Technology** **B3：数字信息和自动化技术的趋势** **Moderator: Tia Bush,** Vice President, Quality, *Amgen, Inc.* **主持人：Tia Bush，安进公司质量副总裁**	**IG5: Cell and Gene Therapy** **IG5：细胞和基因治疗** **Leaders: Michael Blackton, MBA,** Vice President, Global Quality, *Adaptimmune, LLC* and **Vijay Chiruvolu, PhD,** Vice President, Process Sciences & Engineering, *Kite Pharma* **组长：Michael Blackton，MBA，Adaptimmune公司全球质量副总裁和Vijay Chiruvolu，博士，Kite Pharma公司工艺科学和工程副总裁**	**IG6: Facilities and Engineering** **IG6：设施和工程** **Leader: Shelley Preslar, MBA, PMP,** General Manager, *Azzur Group* **组长：Shelley Preslar，MBA，PMP，Azzur集团总经理**
Session Description: High production costs, patient affordability and accessibility, and maintaining an uninterrupted supply of product are primary concerns of the biopharmaceutical industry. To address these issues, the term *agile bioprocessing* might best describe the next evolution needed for biopharmaceutical manufacturing. Indeed, industry efforts are now being directed towards reducing the long development cycle times, increasing production flexibility and eliminating processing complexities all with an aim towards addressing current challenges. This session explores innovative approaches being considered for future biopharmaceutical manufacturing operations, with an emphasis on latest developments in continuous bioprocessing. 描述：高生产成本、患者的负担能力和可及性以及保持产品的不间断供应是生物制药行业的主要关注点。为了解决这些问题，敏捷生物工艺这个术语也许可以最好地	**Session Description:** The healthcare industry is experiencing unparalleled change. Millions of data points are generated throughout the end-to-end supply chain that can be converted to knowledge and understanding that leads to meaningful and timely action to improve manufacturing processes and drive organizational efficiency. A comprehensive digital strategy and structured data analytics can explore techniques such as visualization, modeling, automation, machine learning, and artificial intelligence to dematerialize manufacturing processes and facilities and drive productivity through fewer errors, higher output, and improved quality, safety, and speed. This session will explore case studies where companies have advanced their digital strategy to deliver meaningful value and advancements to the business. 描述：医疗行业正在经历前	**Session Description:** The session will introduce the first program for the Cell and Gene Therapy Interest Group. This session will: **描述：**这个部分将介绍细胞和基因治疗兴趣小组的第一个项目。这个部分将： • Outline the objective and mission of the Cell and Gene Therapy Interest Group. • Introduce and solicit volunteers for a new Technical Report, *Process Validation for Cell Therapy.* • Provide a 30-minute presentation on risk assessment for aseptic processing for cell therapy. This presentation will be a case study and set of recommendations for the establishment of an effective aseptic processing verification program for these innovative products.	**Session Description:** The Facilities and Engineering Interest Group can cover many specific technical interests within the industry as they relate to Manufacturing Facilities and Engineering capabilities. There has been a tremendous amount of discussion around Aging Facilities the past couple of years, so for this meeting, the focus will shift to look at innovation. During the B2 session, we heard about two different approaches to improving aseptic manufacturing capabilities. In this IG session, we will continue to talk with those speakers to take a bit of a deeper dive into their presentations to learn more about their specific examples. 描述：设施和工程兴趣小组可能会涵盖行业中的很多具体技术兴趣，因为它们与制造设施和工程能力有关。在过去几年里对敏捷设施进行了大量讨论，因此在这次会议上，重点

描述生物制药所需的下一次进化。事实上，行业正在努力缩短较长的开发周期，提高生产灵活性和降低工艺复杂性，以应对当前面临的挑战。这部分将探讨用于未来生物制药运营的创新方法，并重点关注连续生物工艺的最新发展。	所未有的变革。在端到端供应链中产生了数以百万计的数据点，这些数据点可以转化为知识和认知，从而产生具有意义和及时的行动，以改进制造工艺并提高组织效率。一个全面的数字策略和结构化数据分析可以探索可视化、建模、自动化、机器学习和人工智能等技术，通过减少错误、扩大输出和提高质量、安全性、速度来使制造工艺和设施非物质化并提高生产效率。这个部分将会对案例研究进行探讨，在这些案例中，提出数字策略的各家公司为业务提供了有意义的价值和进步。	• 概述细胞和基因治疗兴趣小组的目标和任务。 • 介绍“细胞治疗工艺验证”新技术报告并征集志愿者。 • 对细胞治疗无菌工艺提供30分钟的风险评估演讲。本演讲包括一个案例研究和一系列建议，旨在为这些创新产品建立有效的无菌工艺验证程序。	将转向创新。在B2会议中，我们听到了提高无菌制造能力的两种不同方法。在这场IG会议中，我们将继续与演讲者展开讨论，进一步深入探索他们的演讲，以了解更多具体例子。
4:00 p.m. -4:30 p.m. **Continuous Processing Strategies - nextBioPharmDSP** **连续工艺策略－next BioPharmDSP** **Gorazd Hribar, PhD** Project Manager Next BioPharm DSP and Research Scientist, Lek, A Sandoz Company **Gorazd Hribar，博士** Next BioPharm DSP项目经理，Sandoz子公司*Lek*公司研发科学家	4:00 p.m. -4:30 p.m. **New Approaches to Harnessing Data at a Portfolio Level** **在投资组合上利用数据的新方法** **Greg Naugle, MS,** Executive Director, Lead Drug Substance Technology and Engineering, *Amgen, Inc.* **Greg Naugle, 理科硕士** *安进*公司执行总监，药物技术与工程负责人 **Paul Stey, PhD**, Biomedical Data Scientist, *Brown University* **Paul Stey，博士** 布朗大学生物医学数据科学家		**Speaker:** **演讲者：** **Guenther Gapp, PhD,** Consultant, *Gapp Quality GmbH* **Guenther Gapp, 博士** *Gapp Quality 公司顾问* **Panelists:** **小组成员** **Terrence E. Hollis,** Process Engineering Manager, *Patheon* **Terrence E. Hollis,** *Patheon*公司工艺工程经理

4:30 p.m. -5:00 p.m. **Streamlining Biopharmaceutical Decision-Making: Designing for Manufacturability, Facility Fit and Cost-Effectiveness** **简化生物制药决策-按照可制造性、设施安装和成本效益进行设计** **Suzanne Farid, PhD, CEng, FIChemE,** Co-Director, Future Targeted Healthcare Manufacturing Hub, Department of Biochemical Engineering, *University College London* **Suzanne Farid，博士，特许工程师，FIChemE，伦敦大学学院生物化学工程系未来目标医疗制造中心联合主任** 5:00 p.m. -5:30 p.m. **Questions and Answers/Discussion** **问答/讨论**	4:30 p.m. -5:00 p.m. **Industry Perspective on Automated Technology** **对自动化技术的行业视角** **Industry Presenter Invited** **已邀行业演讲者** 5:00 p.m. -5:30 p.m. **Questions and Answers/Discussion** **问答/讨论**		**Ute Schleyer, PhD,** Project Manager, Plant and Site Development, *Vetter Pharma-Fertigung GmbH & Company KG* **Ute Schleyer，博士，***Vetter Pharma-Fertigung GmbH & Company KG***工厂和现场开发项目经理**

5:30 p.m. - 6:30 p.m.
Happy Hour in the Exhibit Hall
展示厅娱乐时间

Wednesday, March 21 3月21日，星期三

7:30 a.m. - 3:15 p.m.
Registration Open 注册

7:30 a.m. - 8:30 a.m.
Continental Breakfast 欧式早餐

7:30 a.m. - 1:45 p.m.
Speaker Ready Room Open演讲者准备室开放

8:30 a.m. - 9:00 a.m.
2019 Annual Meeting Exhibit Space Draw Meeting 2019年年会展区抽签会议

8:30 a.m. -10:00 a.m. **P4: Increasing Capacity and Capability without Increasing Costs** **P4：在不增加成本的情况下提高容量和能力** **Moderator: Maik W. Jornitz, MS,** CEO, *G-Con Manufacturing* **主持人：Maik W. Jornitz，理学硕士，G-Con Manufacturing公司首席执行官**
Session Description: In the past capacity and capability increases meant lengthy, but especially cost intensive expansions of rigid production and process infrastructures. New technology platforms, like single-use processes create the ability to increase or utilize the current capacity in a more flexible, but also efficient way. The new process technologies furthermore enable new process models like continuous processing. The factors listed will change our current thinking of investments to be made, capacity flexing and capacity location, to name a few. Examples of such innovative production and processing platforms will be presented as well as the benefits of such. 会议描述：以前容量和能力的提高意味着付出更长时间，特别是刚性生产和工艺基础设施的成本密集型扩展。然而一次性使用工艺等新技术平台却建立了以更灵活有效的方式提高或利用当前容量的能力。这种新的工艺技术可以进一步推动连续加工等新的工艺模式。列出的因素将会改变我们目前对投资、容量灵活性和容量定位等方面的看法。介绍这些创新生产和工艺平台的例子及其益处。

8:30 a.m. -9:00 a.m.
Transforming Operations with Next-Generation Biomanufacturing
用下一代生物制造技术改变运营
Arleen C. Paulino, Vice President, Singapore Site Operations, *Amgen, Inc.*
Arleen C. Paulino，安进公司新加坡现场运营副总裁

9:00 a.m. - 9:30 a.m.
Improving Operational Performance Using a Resilience Engineering Approach: A Case Study
使用弹性工程方法提高运营业绩：案例研究
Amy D. Wilson, PhD, Director, Global Human Performance, *Biogen*
Amy D. Wilson，博士，百健公司全球人类绩效总监

9:30 p.m. -10:00 a.m.
Questions & Answers/ Discussion
问答/讨论

9:45 a.m. - 1:45 p.m.
Exhibit Hall Open
展示厅开放

10:00 a.m. -10:45 a.m.
Refreshment Break and Poster Presentations in Exhibit Hall
茶歇和展示厅海报展示

10:45 a.m. -12:15 p.m.
Concurrent Sessions 并行会议

Track: Innovative Manufacturing Strategies 分论坛：创新制造策略	**Track: Handling Complexity in the Product Value Chain 分论坛：处理产品价值链中的复杂性**	**Interest Group 兴趣小组**	**Interest Group 兴趣小组**
A4: Implementing Manufacturing Innovation **A4：实施制造创新** **Moderator:** **Ursula Busse, PhD**, Head Quality Intelligence, External Relations, *Novartis* **主持人：** **Ursula Busse，博士，诺华外部关系质量情报负责人**	**B4: Addressing Unique Challenges of Patient Centric Supply Chain Needs** **B4：应对以患者为中心的供应链需求的独特挑战** **Moderator: Karen Walker,** Vice President, Quality, *Seattle Genetics* **主持人：Karen Walker，Seattle Genetics质量副总裁**	**IG7: Visual Inspection of Parenterals** **IG7：注射用药物的视觉检测** **Leader: John G. Shabushnig, PhD,** Principal Consultant, *Insight Pharma Consulting, LLC* **组长：John G. Shabushnig，博士，Insight Pharma Consulting公司首席顾问**	**IG8: Combination Products** **IG8：组合产品** **Leader: Lee Leichter,** President, *P/L Biomedical* **组长：Lee Leichter，P/L Biomedical总裁**
Session Description: Innovation in manufacturing should be at the heart of our efforts to ensure the sustained supply of better, safer medicines to patients. Yet our industry is very slow in adopting the wealth of new manufacturing technologies available. This session will discuss strategies for successful implementation of innovative technologies in pharmaceutical manufacturing, focusing on challenges, success factors and key learnings. Presentations will cover both the technical as well as the cultural and leadership aspects of implementation. 描述：制造创新应当是我们努力的核心，以确保向患者持续供应更好、更安全的药品。但是我们行业在采用可用的新制造技术方面仍然非常缓慢。这部分将讨论在医药制造领域成功采用创新技术的策略，重点关注挑战、成功因素和关键知识。 演讲将涵盖实施的技术、文化和领导方面。	**Session Description:** With the recent approval(s) of (a) CAR-T therapies in the US, and the explosion in the research into these types of therapies, there are over 300 trials listed on ClinicalTrials.gov, and over 40 active. CAR-T is not the only Patient Centric therapy being developed, and with this increase in active clinical studies, there is increased attention on managing the supply chain for these types of products. Hear stories from leaders in the personalized medicine space on how they are approaching the challenges of patient identity, supply chain security, cost, speed, importation, exportation, and other challenges unique to these programs. 描述：随着CAR-T治疗方法最近在美国获批以及对此类治疗的研究激增，在ClinicalTrials.gov上列出了300多个临床试验，有40多个处于活跃状态。CAR-T并不是开发的唯一一个以患者为中心的治疗方法，并且随着它在活动临床研究中的增加，对这些类型产品的供应链管理给予了更大关注。倾听个性化医疗领域各家领先企业的故事，了解他们如何应对患者身份、供应链安全、成	**Session Description:** This Interest Group session will focus on the inspection of injectable products, specifically those considered “difficult to inspect” such as lyophilized powders, suspensions and protein solutions, as well as those in amber glass or plastic containers. A review of the recently published PDA Technical Report on this subject will be included in the agenda. A brief presentation reviewing relevant recalls, warning letters and 483 observations will be given followed by a moderated discussion on inspection topics of interest to those in attendance. Past discussions have included current experience with USP <790> and <1790>, selection and training of inspectors who perform manual inspection, industry benchmarks for inspection practices and inspection results. 描述：这个兴趣小组将重点关注可注射产品的检测，特别是那些被认为“很难检测”的产品，如冻干粉、悬浮液和蛋白质溶液，以及装在棕色玻璃瓶或塑料容器中的产品。在议程中	**Session Description:** This session will include a discussion of the concepts, expertise, expectations, and requirements for a pharmaceutical company to develop, manufacture, and market a combination product. Topics will include areas, such as: 描述：这个部分将包括对制药公司开发、制造和销售组合产品的概念、专知、期望和要求的讨论。 主题将包括以下领域，例如： • Design Controls • Mechanical/Electronic Engineering • Risk Management • Human Factors Engineering • Device Software Engineering, validation and controls • Mobile Medical Applications • Medical Device Reports (MDRs) • Device Purchasing Controls • Change Management for devices • Functional Stability • Drug Compatibility • 设计控制 • 机械/电子工程 • 风险管理 • 人为因素

	本、速度、输入、输出挑战以及这些项目中的其他独特挑战。	将包括回顾最近对该主题发布的PDA技术报告。将通过一个简短的介绍回顾相关的召回、警告信和483项观察结果，随后对与会者感兴趣的检测主题进行适当讨论。过去的讨论已经包括了USP <790>和<1790>选择的当前经验以及对进行人工检测的检测人员的培训、检测实践方法的行业基准和检测结果。	• 设备软件工程、验证和控制 • 移动医疗应用 • 医疗设备报告（MDR） • 设备采购控制 • 设备变更管理 • 功能稳定性 • 药物相容性 This session will help attendees gain an appreciation for the challenges of successfully developing, manufacturing, and marketing a combination product within the pharmaceutical company environment. 这部分将帮助与会者了解在制药公司的环境中成功开发、制造和销售组合产品面临的挑战。

10:45 a.m. -11:15 a.m. **Next Generation Advancements – Treatment Modalities, Innovative Manufacturing and Novel Attribute Assessments** **下一代发展——治疗方式、创新制造和新属性评估** **Michael Abernathy,** Executive Director, Regulatory Affairs CMC, *Amgen Inc.* **Michael Abernathy，安进公司监管事务CMC执行总监** 11:15 a.m. -11:45 a.m. **The Human Side of Innovation** **创新的人性考量** **Pierre Boulas, PhD,** Senior Director, Pharmaceutical Development, *Biogen* **Pierre Boulas，博士，百健公司药品开发高级总监** 11:45 a.m. -12:15 p.m. **Questions and Answers/Discussion** **问答/讨论**	10:45 a.m. -11:15 a.m. **Perspective on Patient-Centric Supply Chain Needs** **患者视角——中心供应链需求** **J. Andrew Case,** Director, Supply Chain Emerging Technology, *Novartis Pharmaceuticals Corporation* **J. Andrew Case，诺华供应链新兴技术总监** 11:15 a.m. -11:45 a.m. **Intelligent Biomanufacturing and the Impact on Facility Design on the Factory of the Future** **智能生物制造以及对未来工厂设施设计的影响** **Jeffery Odum,** Global Technology Partner, *NNE* **Jeffery Odum，NNE全球技术合作伙伴** 11:45 a.m. -12:15 p.m. **Questions and Answers/Discussion** **问答/讨论**		

12:15 p.m. - 1:45 p.m.
Networking Luncheon and Passport Raffle in Exhibit Hall
交流午宴和展示厅护照抽奖活动

1:45 p.m. - 3:15 p.m.
P5: Personalized Medicine
P5：个性化药品
Moderator: Ghada Haddad, MBA, Executive Director, Global GMP Auditing, *Merck Sharpe & Dohme*
主持人：Ghada Haddad，MBA，默沙东全球GMP审计执行总监

Session Description: Until now, most medical treatments have been designed for the "average patient." Because of this "one-size-fits-all" approach, treatments can be very successful for some patients but not for others. Precision Medicine, on the other hand, is an innovative approach that considers individual differences in people's genes, environments, and lifestyles. It gives medical professionals the resources they need to target the specific treatments of the illnesses we encounter, further develops our scientific and medical research, and keeps our families healthier. Advances in Precision Medicine have already led to powerful new discoveries and several new treatments that are tailored to specific characteristics, such as a person's genetic makeup, or the genetic profile of an individual's tumor. This is helping transform the way we can treat diseases such as cancer: Patients with breast, lung, and colorectal cancers, as well as melanomas and leukemias, for instance, routinely undergo molecular testing as part of patient care, enabling physicians to select treatments that improve chances of survival and reduce exposure to adverse effects.
描述：至今为止，大部分医疗都是为"普通患者"设计的。由于采用这种"普适"的方法，治疗对某些患者来说非常成功，但对其他患者却并非如此。精准医疗是一种创新方法，考虑到了人的基因、环境和生活方式的个体差异。它为医学专业人员提供了对症治疗的必要资源，进一步发展科学和医学研究，并且使我们的家人更健康。精准医疗的进步已经带来了重大的新发现和针对具体特性的几项新治疗方法，例如某个人的基因构成或者某个肿瘤的基因档案。这将有助于改变我们治疗癌症等疾病的方式：乳腺癌、肺癌、结肠癌以及黑色素瘤和白血病患者，作为患者护理的一部分，定期进行分子测试，从而使医生可以选择适当的治疗方式，提高生存机会和减少副作用。
In the last few years, we have seen a rapid development of new methods using immunotherapies in treating different

types of cancer. By combining immunotherapy with other types of treatment, an increase of the effectiveness may be accomplished. Newer types of immune treatments are now being developed, and they will affect how we treat cancer in the future. This session will explore more about the status of where pharma development is today as well as example of a successful research.
在过去几年里，我们看到了在治疗不同类型的癌症时新免疫疗法的迅速发展。通过将免疫疗法与其他类型的治疗结合，可以提高疗效。目前，正在开发更新的免疫疗法，它们将影响我们未来治疗癌症的方式。这部分将进一步探讨医药发展的现状并对成功研究进行举例说明。

1:45 p.m. - 2:15 p.m.
Personalized Cancer Vaccines
个性化癌症疫苗
Rainer Mueller, PhD, Project Leader Custom Biotech, Vice President, *Roche Diagnostics GmbH*
Rainer Mueller，博士，罗氏诊断有限公司副总裁，定制生物技术项目负责人

2:15 p.m. - 2:45 p.m.
Polio Virus Vaccine Trial
脊髓灰质炎病毒疫苗试验
Matthias Gromeier, MD, Professor, Department of Neurosurgery, *Duke University Medical School*
Matthias Gromeier，医学博士，杜克大学医学院神经外科学系教授

2:45 p.m. - 3:15 p.m.
Questions and Answers/ Discussion
问答/讨论

3:15 p.m.
Closing Remarks & Adjournment from Co-Chairs of the 2019 PDA Annual Meeting Program Planning Committee
2019年PDA年会议程筹备委员会联合主席致闭幕辞&休会
Ghada Haddad, Executive Director, Global GMP Auditing, *Merck & Company/Merck Sharpe & Dohme*
Ghada Haddad，默克公司/默沙东全球GMP审计执行总监

7:00 p.m. - 10:00 p.m.
Closing Reception
闭幕招待会