Lecturers biography

PFSS2021Tokyo

A-1　招待講演者

公益財団法人 医療機器センター
Japan Association for the Advancement of Medical Equipment
JAAME

上級研究員　　石黒 克典

演題：プレフィルドから見た医療機器規制

内容

1. **改正薬事法および改正QMS**
2. **医療機器開発における規格・基準**
   QMS、リスクマネジメント、HF
3. **医薬品注入器等の規制概要**

経歴

1974年～	株式会社仁丹テルモ（現 テルモ株式会社）にて薬事申請業務、企画・渉外業務。業界団体の薬事法制を担当。
2010年～	株式会社ジェイ・エム・エスにて薬事業務。 業界団体の薬事法制を担当。
2013年～	現職

A-2

Senior Manager, Regulatory Affairs
Pharmaceutical Systems,
Becton Dickinson Co. Ltd.,

- Alison Bascou is currently Senior Regulatory Affairs Manager at BD Medical-Pharmaceutical Systems located in France for US, Europe, Latin America & Greater Asia. In her current role, she leads a team dedicated to supporting customers in their WW registrations of drug-device combination products and medical devices.
- Prior to this role, she held positions of increasing responsibility in customer facing teams and innovation product projects. Prior to joining BD in 2012, she worked in generic pharmaceutical companies in France and Germany.
- Alison Bascou holds a PhD in Chemistry from the RWTH University of Aachen (Germany), a Chemical Engineering degree from the Ecole Centrale in Marseille (France) as well as a Master in Health & Law from Paris XI (France).

B-1　Dr.　James Hathcock

James Hathcock, PhD
Senior Director
Regulatory and Validation Strategy
Pall Biotech (New York)

- Responsible for regulatory and validation strategy for single-use technologies
- Leads BPSA initiative on X-ray qualification for single-use disposables, the BioPhorum Community of Practice for Extractables and leachables, ASME-BPE task group on Flexible Biocontainers, and is an expert panel member for USP <665> & <1665>. Is also an active member of ASTM, ASME-BPE, PDA, ISPE and BPSA
- Prior to joining Pall, James served as professor of hematology at the Mt. Sinai School of Medicine in New York City, where he directed protein purification related to drug characterization and discovery.

B-2 Thierry GIRARD (ABC TRANSFER)

President at ABC Transfer

Thierry has co-founded ABC Transfer in 2019 in Tours (France)

Before that he has worked from 1991-2018 in various manufacturing, sales and marketing positions in France and in the UK in the automotive, food and pharmaceutical Industries.
These roles included a CEO position at Getinge La Calhène and a site management position at Fresenius SMAD.

Thierry has received his engineering degree from INSA in 1988.

B-3　Eng. Rajeev Kabbur

Director of Sales, Marketing and R&D
at Brevetti Angela S.r.l.

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- Rajeev Kabbur earned a degree of Mechanical Engineer and MBA at Birla Institute, India. With over 25 years of experience in the pharmaceutical field, has a solid background in sterile and aseptic production facilities for injectables, intravenous fluids, Hemofiltration and Ophthalmic products.
- He joined Brevetti Angela in 1998 and since then, he's been actively working on the development of innovative solutions on Blow Fill Seal machines. He has also worked as Chief Production Planning in Fresenius Kabi Italia, Validation Manager at SIFRA (Italy), Chief Engineer at Iveon Laboratories and Maintenance Engineer at Indian Rayon Ltd., India.
- Eng. Kabbur has been a speaker at PDA, BFS IOA, ISPE, VacChina, Management Forum, Hexagon, among other Conferences and Meetings. There are several products/technologies patented under his name.

C-1 Dr. Benjamin Ledermann(GEA Lyophil)

Dr. Benjamin Ledermann
Expert Freeze Drying Technology
Technology Management
GEA Lyophil GmbH

- Dr. Benjamin Ledermann received his PhD in Biochemistry and Microbiology from Kaiserslautern University where he also worked as a PostDoc.
- Benjamin joined GEA Lyophil in 2018 as an Expert for Freeze Drying Technology. In his current role at the Technology Managment Department he is involved in the development and evaluation of novel technologies like controlled nucleation solutions and analytical tools for the characterization of freeze-dried products.

C-2 : Dr. Markus Neumeier(Vetter)

Team Mananger Technology & Process Transfer

- Markus Neumeier studied molecular biology and received a PhD in natural science at the University of Regensburg. After joining Development Service Department at Vetter Pharma-Fertigung GmbH he has focused on development and implementation of pharmaceutical processes. He is heading a team of experts for lyophilized products and double chamber systems.

- Meetings (as invited speaker):
- Pharmakongress 2016, Duesseldorf, Germany
- Pre-filled syringe seminar 2018, Tokyo, Japan

Voice From EU：Dr.　Georg Roessling

SENIOR CONSULTANT, BUSINESS
DEVELOPMENT ASIA AT PDA ASIA-PACIFIC

Georg Roessling has been a consultant since 2017. From 2006-2017 he held the position of Sr. Vice President of PDA Europe, where he started the office in Europe and developed a number of conferences and training courses together with regulatory agencies, pharmaceutical industry experts, and suppliers. Before that he worked from 1984-2005 with Schering AG; Germany in various positions. These roles included head of pharmaceutical development of parenterals and head of Global CMC Technology office.

Georg is a chemist by training, has a PhD in Physical chemistry from the university of Karlsruhe and was a post-doc in Chemical Engneering at Berkeley, USA. He is a PDA member for almost 30 years and he received the PDA Honorary Membership.

Voice From USA：Dr. Amy Wang

Amy Wang, PhD（王惠蓉博士）
Director
Drug Delivery and Device Development
Alexion/ AstraZeneca Rare Disease

- Dr. Amy Wang received her PhD in Materials Science & Engineering from University of Michigan. Prior to Alexion/ AstraZeneca Rare Disease, she worked for Abbott, Amgen and Biogen.
- Her biopharmaceutical experience spans from clinical to post market life cycle management, including medical device/combination products that integrates drug delivery and user interface for competitive edge and patient convenience.

F-1
Erik Berndt & Peter Schmidt (ZwickRoell)

Mr. Erik Berndt
Industry Manager

Mr. Peter Schmidt
Product Manager

Mr. Erik Berndt

1997-2003 RWTH Aachen University,Head Research Group Biomaterials/Implants

2003-2008 Paul Hartmann AG, Heidenheim,

Head of R&D Compression/Immobilization products

2008- Zwick Rowll Industry Manager

Mr. Peter Schmidt

1993 Degree in Biomedical Engineering, University of Applied Sciences Ulm

Cardiac Catheter Laboratory

GE Medical Systems, Freiburg, Germany

HWP Planungsgesellschaft, Stuttgart Germany

2018-ZwickRoell GmbH & Co KG,

G-1 Mr. Paolo Golfetto(Stevanato Group)

Director of Business Development,
Drug Delivery Systems – Stevanato Group

Paolo Golfetto is the Director of Business Development, Drug Delivery Systems at Stevanato Group. In his position, he leads the development and execution of the business strategy in the drug delivery system field, supports the external technical communication of the global product platforms and manages project acquisition and transfer to the internal development structures, securing the integration of the different capabilities of the group. Before taking this position, Mr. Golfetto was the Primary Packaging Development & Customer Care Director, leading new glass packaging introduction and technical support to the group's biopharmaceutical clients. Mr. Golfetto is a PDA member and lecturer.

G-2 Frank Bamberg(CSL Behring) & Tom van Ginneken (SCHOTT)

Frank Bamberg

Associate Director
for Medical Device
and Primary Packaging

Tom van Ginneken

- Frank Bamberg
- Frank Bamberg has close to 20 years' experience in the pharmaceutical industry in various leading roles such as in research & development, business development, and project management. Frank holds an MBA in Industrial Engineering and Management from the University of Bern/Zürich

- Tom van Ginneken
- After working in the chemical and pharmaceutical sector in Belgium for 3 years he joined SCHOTT in 2008.
- Pharmaceutical product development department, The product management team with focus on the SCHOTT TOPPAC®, The Polymer Design Platform.

G-3 岩瀬陽一郎（テルモ）

- 略歴：2003年立命館大学総合理工学専攻、早期修了、博士（工学）取得。産業技術総合研究所関西センター光技術研究部門特別研究員を経て、2005年テルモ（株）に入社。2007年皮内投与型デバイス（イムサイス™）における研究開発を開始し、製品化を完了。現在、R&D部門において、新規コンビネーションデバイスの研究開発に従事。
- 専門分野：医療機器を主とする新規コンビネーションデバイスの研究開発（企画・FS・設計・量産化・品質保証・薬事申請・QMS）

テルモ株式会社　ホスピタルカンパニー
アライアンス事業 R&D部門　上席主任研究員/博士（工学）

H-1　Dr. James　Veale　(Lighthouse)

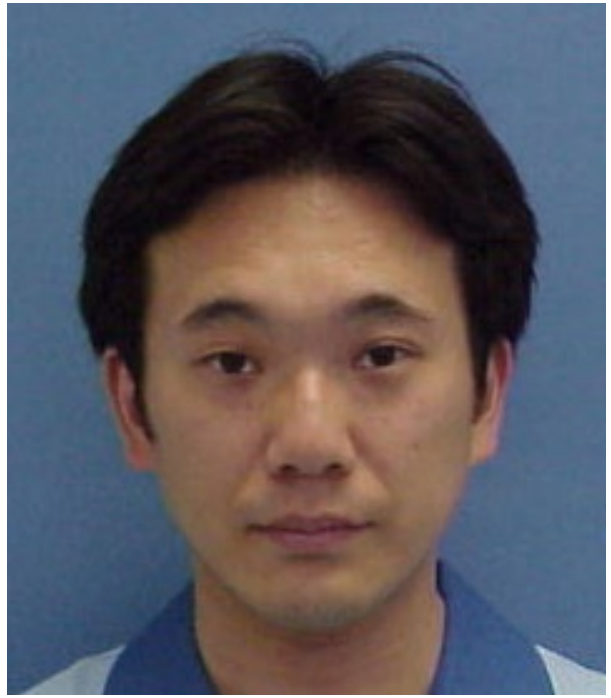
Jim Veale, PhD
President and Founder,
Lighthouse Instruments

Dr. Veale received a PhD in Atomic, Molecular and Optical Physics from the University of Virginia.

He founded Lighthouse Instruments in 1995 to apply laser spectroscopic methods to unmet needs in the pharmaceutical industry.

His research interests focus on container closure integrity and sterile product fill/finish process monitoring.

I-1:水上　佳也 (中外製薬)



- 略歴

1995年～	雪印乳業株式会社（現雪印メグミルク株式会社）にて生産技術、包装開発業務を担当。
2004年～	マスターフーズリミテッド（現マースジャパンリミテッド）にて包装開発業務を担当
2006年～	中外製薬株式会社にて、包装開発業務担当を経たのち、現在はデバイス開発業務を担当