Dear Colleagues,

We welcome you to the conference “Current Trends in Aseptic Fill & Finish of Pre-filled Syringes” in Lindau/Bodensee (Lake Constance), Germany.

This conference gives you a broad overview of current best practice in Aseptic Processing with a focus on Fill & Finish of pre-filled syringes, including the current technical and regulatory trends. The first day starts with quality culture and metrics topics and how to integrate these into the manufacturing environment of today and tomorrow. Industry 4.0 and the impact of digitalization and barrier technology are further topics. In the afternoon, there will be a site visit at Vetter in Ravensburg to see Aseptic Manufacturing and packaging for syringes. In parallel, there will be a workshop at the hotel on the future of Aseptic Manufacturing, including ready-to-use concepts, RABS and Isolator Technology.

The second day will start with a presentation of a GMP inspector, who will share insights from inspections, followed by first thoughts about the new EU GMP Annex 1 draft. Further presentations will focus on innovations in Aseptic Processing, and the conference will be concluded with a presentation on devices and the assembly of syringes into devices. The conference will offer you an overall picture of aseptic processing and handling of pre-filled syringes. We encourage you to fuel the dialogue, ask questions, get involved in discussions: be part of it!

We have planned plenty of opportunities for you to network and interact with your peers: refreshment breaks, luncheons and an evening reception. Don’t miss the accompanying exhibition – all breaks will be served in the exhibition area – so take the opportunity to meet our exhibitors and catch up with the latest industrial developments.

Welcome to Lindau!

Brigitte Reutter-Haerle, Vetter
Conference CoChair

Georg Roessling, PDA Europe
Conference Co-Chair
THE PARENTERAL DRUG ASSOCIATION & VETTER PHARMA ARE PROUD TO INVITE YOU TO A VERY SPECIAL

Networking Event

WHERE?
Wissingers im Schlechterbräu,
In der Grub 28,
88131 Lindau (Bodensee)

WHEN?
26 April
19:00 - 21:30 h

15 minutes, walking distance from the conference hotel
We meet in the hotel lobby at 18:45 h

Traditional BAVARIAN EVENING

Take this opportunity to meet new people from our industry while enjoying regional food & drinks!
# CONFERECE AGENDA

**Wednesday, 26 April 2017**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:00</td>
<td>Welcome and Introduction</td>
<td>Georg Roessling, PDA Europe Brigitte Reutter-Haerle, Vetter</td>
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<tr>
<td>9:05</td>
<td>Quality Culture &amp; Quality Oversight from a Regulatory Perspective</td>
<td>Stephan Roenninger, Amgen</td>
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<tr>
<td>9:30</td>
<td>Quality Metrics: Effectiveness of Processes and Systems</td>
<td>Philip Hoersch, Vetter</td>
</tr>
<tr>
<td>10:00</td>
<td>Future Challenges of Flexibility in Aseptic Manufacturing incl. Digitalization &amp; Industry 4.0</td>
<td>Johannes Rauschnabel, Bosch Packaging</td>
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<tr>
<td>10:30</td>
<td>Coffee Break &amp; Exhibition</td>
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<tr>
<td>11:00</td>
<td>Successful Tech Transfer - a Case Study</td>
<td>Brian Thome, Biogen</td>
</tr>
<tr>
<td>11:30</td>
<td>Clean Room Technology - Combined Advantages of Isolators and RABS</td>
<td>Gerald Buerkle, Vetter</td>
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<tr>
<td>12:00</td>
<td>Lunch Break &amp; Exhibition</td>
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<tr>
<td>13:00</td>
<td>SITE VISIT VETTER Aseptic Production and Packaging Site</td>
<td>Moderator: Brigitte Reutter-Haerle, Vetter</td>
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<tr>
<td>13:00</td>
<td>WORKSHOP IN HOTEL Isolators/RABS/Ready-to-Fill Components</td>
<td>Moderator: Georg Roessling, PDA Europe</td>
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<tr>
<td>13:00</td>
<td>From Ready-to-Fill Glass Containers to a Full Set for High Performance Fill &amp; Finish Modules</td>
<td>Lorenza Bonaldi, OMPI</td>
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<tr>
<td>14:00</td>
<td>Q&amp;A, Discussion</td>
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<tr>
<td>14:30</td>
<td>Coffee Break &amp; Exhibition</td>
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</tbody>
</table>

**Plenary: Future Challenges & Opportunities**

Moderator: Brigitte Reutter-Haerle, Vetter

Heightened quality and oversight metrics for processes and systems and a need for greater flexibility in aseptic manufacturing for pharmaceutical companies are current challenges. Can improved technology and digitalization be the pathway to the future of drug manufacturing?

Visit of an aseptic manufacturing facility for syringes, vials and cartridges. The Site Visit is split in two different parts [A]+[B] and offers:

[A] First-hand, V-CRT® Technology, which combines advantages of RABS and isolator technology as well as methods to end up in filling lines with highest quality and highest flexibility.

[B] In the secondary packaging facility, attendees will learn about different options for the packaging of aseptic drug delivery systems to serve different world markets.

This workshop deals with best practice solutions of aseptic processing using ready-to-fill components in a barrier environment. Especially cleaning and disinfection challenges in isolators will be addressed.

**SITE VISIT VETTER**

Moderator: Brigitte Reutter-Haerle, Vetter

Visit of an aseptic manufacturing facility for syringes, vials and cartridges. The Site Visit is split in two different parts [A]+[B] and offers:

[A] First-hand, V-CRT® Technology, which combines advantages of RABS and isolator technology as well as methods to end up in filling lines with highest quality and highest flexibility.

[B] In the secondary packaging facility, attendees will learn about different options for the packaging of aseptic drug delivery systems to serve different world markets.
<table>
<thead>
<tr>
<th>Time</th>
<th>Site Visit Vetter (Continued)</th>
<th>Workshop in Hotel (Continued)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15:00</td>
<td>[A] Aseptic Production</td>
<td>15:00 RABS &amp; Isolator Technology</td>
</tr>
<tr>
<td></td>
<td>[B] Packaging Site VSP</td>
<td></td>
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<tr>
<td>16:00</td>
<td>Refreshment Break and Transfer to other Site</td>
<td>15:45 Cleaning &amp; Disinfection / H₂O₂</td>
</tr>
<tr>
<td>16:30</td>
<td>[B] Packaging Site VSP</td>
<td>16:45 Q&amp;A, Discussion</td>
</tr>
<tr>
<td></td>
<td>[A] Aseptic Production</td>
<td></td>
</tr>
<tr>
<td>17:30</td>
<td>Transfer to Conference Hotel</td>
<td>17:30 Summary &amp; End of Day 1</td>
</tr>
</tbody>
</table>

18:45 Networking Dinner Event in Lindau  
Meeting Point: Lobby

**Thursday, 27 April 2017**

**Plenary: Regulatory & Manufacturing Trends**

*Moderator: Georg Roessling, PDA Europe*

Be among the first to hear the Annex 1 draft results and learn more about the trends and challenges affecting the future of aseptic manufacturing, including gloveless isolators, final packaging, and syringe assemblies that offer the highest degree of flexibility.

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:15</td>
<td>Inspection Results, Annex 1 Draft</td>
<td>Daniel Mueller, GMP Inspector, Germany</td>
</tr>
<tr>
<td>10:00</td>
<td>Q&amp;A, Discussion</td>
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<tr>
<td>10:30</td>
<td>Coffee Break &amp; Exhibition</td>
<td></td>
</tr>
<tr>
<td>11:00</td>
<td>Gloveless Isolators</td>
<td>Aidan Harrington, DPS Engineering</td>
</tr>
<tr>
<td>11:30</td>
<td>Innovation in Parenteral Filling – A Pharma Perspective</td>
<td>Chi Yuen Liu, Janssen J&amp;J</td>
</tr>
<tr>
<td>12:00</td>
<td>Panel Discussion: Future Challenges for Aseptic Manufacturing – Quality, Regulatory and Business</td>
<td>Georg Roessling, PDA Europe</td>
</tr>
<tr>
<td>13:00</td>
<td>Lunch Break &amp; Exhibition</td>
<td></td>
</tr>
<tr>
<td>14:00</td>
<td>Trends &amp; Challenges to Offer Flexibility in Packaging (Manual/Automatic, Pen/Auto Injector)</td>
<td>Ian Thompson, Ypsomed</td>
</tr>
<tr>
<td>14:30</td>
<td>Reliable Syringe Assembly with the Highest Degree of Flexibility</td>
<td>Markus Rothen, INSYS</td>
</tr>
<tr>
<td>15:00</td>
<td>Q&amp;A, Discussion</td>
<td></td>
</tr>
<tr>
<td>15:30</td>
<td>End of Meeting &amp; Farewell</td>
<td></td>
</tr>
</tbody>
</table>
From clinical development to commercial production

Your strategic partner in aseptic filling

Vetter is a leading contract development and manufacturing organization (CDMO) that specializes in the aseptic filling of syringes, cartridges and vials. Vetter holds numerous patents and has extensive experience with biologics and other complex compounds, including monoclonal antibodies, peptides, interferons and vaccines. More than 70% of Vetter’s active projects are biologics, and Vetter currently manufactures five of the world’s top 10.

Collaborating with the top 10 (bio-)pharmaceutical companies worldwide, Vetter supports products from preclinical development through global market supply. Through its U.S. and European facilities, Vetter Development Service provides state-of-the-art support for early-stage products, with seamless transfer at Phase III to Vetter Commercial Manufacturing for large-scale production. The company offers state-of-the-art technology and innovative processes to promote product quality and maximize API yield.

Contact us:
For US inquiries: infoUS@vetter-pharma.com • For Asia Pacific inquiries: infoAsiaPacific@vetter-pharma.com • For Japan inquiries: infoJapan@vetter-pharma.com • For EU and other international inquiries: info@vetter-pharma.com
Vetter at a glance

- Headquarters in Ravensburg, Germany
- Additional clinical development facility in Chicago, US
- A Representative office for Asia Pacific in Singapore and a subsidiary in Japan
- Approximately 4,100 employees
- Worldwide specialist in the aseptic production of prefilled drug delivery systems
- Global experience and expertise with regulatory authorities including FDA, EMA, PMDA (Japan), and RP (Germany)
- Approx. 50 customer products (drug products and diluents) with FDA approval
EXHIBITION FLOOR PLAN

Table Top 2 m x 2 m (4m²)
Coffee Station

PMS
WILCO
Dara
Afton
Vetter
Lighthouse
Seidenader
Steris
Sartorius Stedim
Ompi
Lourd Innov
Afton Scientific
2020 Avon Ct.
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Tel +1 434 979 3737
Fax +1 434 979 3738
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www.aftonscientific.com

Afton is the world premiere provider of pre-packaged empty sterile vials, stoppers and seals (Ready-to-Fill®) to companies worldwide for immediate use in cGMP aseptic filling operations. These components are used not only for small clinical fills, but also for approved marketed injectable drugs. Afton (DBA AnovaFill) provides cGMP contract sterile filling services of investigative new drugs, biologics, and commercial injectable pharmaceuticals. Capabilities to batch, sterilize, fill, label, and package. We specialize in small batch clinical and commercial runs. Afton’s customers include small biotechs, multinational pharmaceutical companies and major research institutions. Afton ships worldwide.

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Fax. +34 938718375
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www.dara-pharma.com

Since it was founded in 1996, Dara Pharma focused all its effort on quality, innovation and technological excellence. We provide the pharmaceutical, biotech and cosmetic industries with the most advanced technological equipment in the market. We offer a high level of innovation and development along with the capability to adapt each project to the specific needs of the customer. Dara Pharma manufactures washing, sterilizing, filling and closing machines for bottles, vials, cartridges, syringes and bags. These machines process liquids, semi-solid products and powder in sterile conditions. The machines run either individually or can be integrated into a complete production line.

LIGHTHOUSE Instruments
Science Park 408, 1098 XH, Amsterdam, The Netherlands
Tel +31 6 4226 7380
dduncan@lighthouseinstruments.com
www.lighthouseinstruments.com

LIGHTHOUSE is the leading global provider of laser-based, non-destructive headspace inspection systems. LIGHTHOUSE introduced the laser-based headspace method into the pharmaceutical industry in 2000 and offers a range of benchtop and in-line platforms with patented laser sensor technology commercialized with the help of funding from the Food and Drug Administration. In addition to delivering equipment, Measurement Services & Support are delivered from laboratory facilities in Amsterdam and Charlottesville, Virginia. A staff of Application Scientists supports customers with outsourced testing services, scientific studies, and lease equipment projects.

LDI is specialist in aseptic transfer technology for introduction of sterile components or for containment applications in Fill/Finish operations. Our innovative Steripass® concept extend the use of RTP technology to nested components such as RTU primary containers (vials, syringes...).

OMPI - A Stevanato Group Brand
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Fax +39 04 993 18611
info@ompipharma.com
www.ompipharma.com/

OMPI is part of the Pharmaceutical Systems division of Stevanato Group and boasts a unique expertise in providing superior pharmaceutical containers from glass tubing. With operations in Italy, Slovakia, Mexico and China, Ompi offers the widest range of glass primary packaging, from the traditional ones such as vials and ampoules, to the high value ones as syringes and cartridges for auto-injectors and pen-injectors. Vials, cartridges and syringes are available also sterile and ready to fill (Ompi EZ-fill®).

Particle Measuring Systems
5475 Airport Blvd
80301 Boulder, United States
Tel +1 3034437100-217
Fax +1 3034496870
ksternberg@pmeasuring.com
pmeasuring.com

Particle Measuring Systems Inc. (PMS), a subsidiary of Spectris plc, is a global technology leader in contamination monitoring, the inventor of laser particle counting, and now is the leading provider of solutions for monitoring and controlling many forms of contamination that impact companies that manufacture in ultra-clean environments.

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Fax +33 (0)4 42 84 56 19
leads@sartorius.com
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Sartorius Stedim Biotech is a leading provider of cutting-edge products and services for the development, quality assurance and production processes of the biopharmaceutical industry. Its integrated solutions covering fermentation, cell cultivation, filtration, purification, fluid management and lab technologies are supporting the biopharmaceutical industry to develop and produce drugs safely, timely and economically. Sartorius Stedim Biotech focuses on single-use technologies and value-added services to meet the rapidly changing technology requirements of the industry it serves. Strongly rooted in the scientific community and closely allied with customers and technology partners, the company is dedicated to its philosophy of “turning science into solutions.”

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Seidenader is a competent partner to pharmaceutical companies, specialized in solutions for inspection and track&trace. We develop and build inspection machines and applications for manufacturers all over the world. State-of-the-art serialization and aggregation solutions for the traceability of products and for the protection from counterfeiting are part of the comprehensive Seidenader Track&Trace Solutions. As an innovative and well-established company with more than 120 years of experience in the market Seidenader is now one of the leading suppliers for inspection and track&trace solutions, worldwide. Seidenader is part of Medipak Systems, the Pharma Systems business area of the international Körber technology group.

STERIS Life Sciences
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Fax +49 221 466 120 40
andy_todd@steris.com
www.sterislifesciences.com

STERIS Life Sciences provides contamination control solutions to the Pharma, Biopharma and Medical Device manufacturing and R&D sectors on a truly global basis. Our “consumables” offering includes a full range of validatable process cleaning agents and antimicrobial products, biological and chemical indicators. They are backed by highly knowledgeable sales team and a data & support package that is unrivalled in the industry. A new and interesting addition to our product offering includes sterilisation wrapping & packaging, covers, closures, bags, liners and cleanroom tools, incorporating all the benefits of Tyvek. In addition to key process equipment such as washers, sterilisers, Water For Injection and Pure Steam Generation systems, our Capital Equipment group offers proprietary VHP decontamination products. These are backed by a fully developed and responsive Service team to correctly maintain the equipment and ensure maximum up-time. An important service offered is the contract decontamination of manufacturing spaces using our VHP technology, which allows cost effective, validated and rapid preparation of cleanrooms prior to manufacturing. We invite you to visit www.sterislifesciences.com to view your contamination control options. Globally.

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www.vetter-pharma.com

Vetter is a leading contract development and manufacturing organization (CDMO) that specializes in the aseptic filling of syringes, cartridges and vials. The company has extensive experience with biologics and other complex compounds, including monoclonal antibodies, peptides, interferons and vaccines. Collaborating with pharma/biotech clients worldwide, Vetter supports products from pre-clinical development through global market supply. Through its U.S. and European facilities, Vetter Development Service provides state-of-the-art support for early-stage products, with seamless transfer at Phase III to Vetter Commercial Manufacturing for large-scale production. The company offers state-of-the-art technology and innovative processes to promote product quality and maximize API yield.

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5610 Wohlen, Switzerland
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Fax +41 566 184 344
info@wilco.com
www.wilco.com

WILCO AG provides in-line, off-line and laboratory machines with non-destructive testing methods for monitoring the oxygen content and container closure integrity simultaneously. Our patented leak detection methods based on the process analytical technologies (PAT) offers the opportunity for monitoring the finishing processes as well. We have newly implemented Visual Inspection technologies in our portfolio. With CCIT and Visual Inspection WILCO AG now covers all inspection expectations for pharmaceutical products and our customers benefit from WILCO AG’s vast experience in quality inspection.
VENUEN
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www.bayerischerhof-lindau.de

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CONFERENCE REGISTRATION HOURS
Wednesday, 26 April: 8:00 - 17:00
Thursday, 27 April: 7:00 - 10:00

SPECIAL REQUIREMENTS
If you require special accommodations to fully participate, please attach a written description of your needs with your registration form. Specific questions can be directed to registration-europe@pda.org.

PDA EUROPE SUPPORTS THE CHILDREN'S HOSPICE „SONNENHOF”

The Sonnenhof Hospice, located near PDA’s office in Berlin, offers support and assistance to families with children suffering from incurable and/or debilitating diseases. At Sonnenhof, children, together with their families, can spend the time they have left as they wish and find some relief from their suffering. Instead of purchasing expensive gifts for the conference speakers, PDA has decided to donate this amount to the Sonnenhof Hospice. You can also contribute and help us increase the amount, it is easy: buy a package of chewing gums at the registration desk. THANK YOU!

To know more about the Sonnenhof Hospice, please visit www.bjoern-schulz-stiftung.de

PDA EUROPE SUPPORTS THE CHILDREN'S HOSPICE „SONNENHOF”

LOGO SONNENHOF - Farbwerte:
Blau = C 100%/ M 30%/ Y 0%/ K 0%
Gelb = C 0%/ M 25%/ Y 95%/ K 0%
<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Location</th>
</tr>
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<tbody>
<tr>
<td>30 May – 1 June</td>
<td>Virus &amp; TSE Safety Forum</td>
<td>Dubrovnik, Croatia</td>
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<tr>
<td>13 – 14 June</td>
<td>2nd PDA Europe Annual Meeting</td>
<td>Berlin, Germany</td>
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<tr>
<td>27 – 28 June</td>
<td>Advanced Therapy Medicinal Products</td>
<td>Valencia, Spain</td>
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<td>19 – 20 September</td>
<td>Pharmaceutical Freeze Drying Technology</td>
<td>Cologne, Germany</td>
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<tr>
<td>26 – 27 September</td>
<td>Particles in Injectables</td>
<td>Berlin, Germany</td>
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<tr>
<td>26 – 27 September</td>
<td>10th Workshop on Monoclonal Antibodies</td>
<td>Berlin, Germany</td>
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<tr>
<td>10 – 11 October</td>
<td>Pharmaceutical Cold &amp; Supply Chain Logistics</td>
<td>Prague, Czech Republic</td>
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<td>7 – 8 November</td>
<td>The Universe of Pre-filled Syringes and Injection Devices</td>
<td>Vienna, Austria</td>
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<tr>
<td>21 – 22 November</td>
<td>Outsourcing &amp; Contract Manufacturing</td>
<td>Munich, Germany</td>
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*Events with additional Education Program. More information – [www.pda.org/pda-europe](http://www.pda.org/pda-europe)*