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2021 PDA ANNUAL MEETING

EXHIBITOR BUYER'S GUIDE



15-17 MARCH

VIRTUAL EXHIBITION: 15-17 MARCH

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This Buyer's Guide is designed to help you maximize your virtual *2021 PDA Annual Meeting* experience. Use the **Schedule-at-a-Glance** and **Tech Talk schedule** to build your own Conference itinerary. The **Exhibitor Abstracts** and listing of Exhibitors by categories of product and service offerings will make it easier for you to navigate the virtual Exhibit Hall and to select those Exhibitors with which you want to connect.

We have developed this Conference to ensure it delivers the same high-quality content, premier attendee experience, and community-focused networking opportunities you have come to expect. With superior content from thought leaders and plenty of opportunities to connect with peers from all over the world, this remains the premier Conference in the field of pharmaceutical manufacturing.

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Amgen is one of the world's leading biotechnology companies. Amgen is a values-based company, deeply rooted in science and innovation to transform new ideas and discoveries into medicines for patients with serious illnesses. Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

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Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.


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amgen.com


SCHEDULE-AT-A-GLANCE


All times listed in EDT (UTC -4)


MONDAY, 15 MARCH


-  **Opening Plenary**
10:00 – 11:30



 -  **Virtual Exhibition Experience and Posters**
11:30 – 12:30


 -  **Concurrent Sessions Live Panel Discussions and Q&A**
12:30 – 13:15


 -  **Network and Connect**
13:15 – 14:00


 -  **Virtual Exhibition Experience and Posters**
14:00 – 14:45


 -  **Concurrent Sessions Live Panel Discussions and Q&A**
14:45 – 15:30


 -  **Network and Connect**
15:30 – 16:15
-  **Trivia with PDA**
16:15 – 17:15


 -  **Break**
17:15 – 20:15

 -  **Concurrent Sessions Live Panel Discussions and Q&A**
20:15 – 21:00


 -  **Network and Connect**
21:00 – 21:45

 -  **Virtual Exhibition Experience and Posters**
21:45 – 22:30

 -  **Concurrent Sessions Live Panel Discussions and Q&A**
22:30 – 23:15

 -  **Network and Connect**
23:15 – 00:00


TUESDAY, 16 MARCH


-  **Plenary**
10:00 – 11:30

 -  **Virtual Exhibition Experience and Posters**
11:30 – 12:30

 -  **Concurrent Sessions Live Panel Discussions and Q&A**
12:30 – 13:15

 -  **Network and Connect**
13:15 – 14:00


 -  **Virtual Exhibition Experience and Posters**
14:00 – 14:45

 -  **Concurrent Sessions Live Panel Discussions and Q&A**
14:45 – 15:30

 -  **Network and Connect**
15:30 – 16:15
-  **Break**
16:15 – 20:15

 -  **Concurrent Sessions Live Panel Discussions and Q&A**
20:15 – 21:00


 -  **Network and Connect**
21:00 – 21:45


 -  **Virtual Exhibition Experience and Posters**
21:45 – 22:30


 -  **Concurrent Sessions Live Panel Discussions and Q&A**
22:30 – 23:15


 -  **Network and Connect**
23:15 – 00:00


WEDNESDAY, 17 MARCH


-  **Concurrent Sessions Live Panel Discussions and Q&A**
10:00 – 10:45


 -  **Network and Connect**
10:45 – 11:30

 -  **Virtual Exhibition Experience and Posters**
11:30 – 12:30


 -  **Concurrent Sessions Live Panel Discussions and Q&A**
12:30 – 13:15


 -  **Network and Connect**
13:15 – 14:00


 -  **Closing Plenary**
14:00 – 15:45

 -  **Break**
15:45 – 20:15
-  **Concurrent Sessions Live Panel Discussions and Q&A**
20:15 – 21:00

 -  **Network and Connect**
21:00 – 21:45

 -  **Virtual Exhibition Experience and Posters**
21:45 – 22:30

 -  **Concurrent Sessions Live Panel Discussions and Q&A**
22:30 – 23:15

 -  **Network and Connect**
23:15 – 00:00

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TECH TALKS

All times listed in EDT (UTC -4)

Tech Talks are on demand. Watch all or some of the available presentations at a time that is most convenient to you. Representatives from the participating companies will be available to answer questions during the time listed below. Join them for face-to-face, live interaction.

MONDAY, 15 MARCH

13:15 – 14:00

EM and the Implication in the EU GMPs Annex 1

Gilberto Dalmaso, Technical Science Director for Europe and Asia, *Veltek Associates*

The presentation will cover all aspects of environmental monitoring design and execution in pharma cleanrooms. It will present the GMP requirements and regulatory expectations. Finally, monitoring methods and rationales for their implementation will be discussed.

15:30 – 16:15

Gaining Value from a Smart Disinfectant Efficacy Strategy

Donald Singer, Senior Microbiology Technical Consultant, *Ecolab Life Science*

Optimizing and having a cost-saving strategy when developing a disinfection efficacy validation program is smart. Developing the right disinfectant efficacy data package to ensure your disinfection program is effective, and to demonstrate this to regulators is critical. If the right package is created, it may be used by one or multiple site operations. Using recognized and validated methods, applying a 'matrix' approach to select the organisms and surfaces to test, and partnering with an experienced contract laboratory are all critical steps in the process. Understanding your options for generating the data package can be significant towards gaining the most value from your decision.

TUESDAY, 16 MARCH

13:15 – 14:00

Cell & Gene Therapy Aseptic Filling Scalability – Development to Commercial

Ken Rando, Head of Business Development for Cell & Gene Therapy, North America, *ATS/COMECER Inc.*

The growing demand for small batch aseptic filling in cell and gene therapy requires both flexibility and robust quality. We will be discussing examples of COMECER's latest downstream filling solutions for both vial and cryo-bag filling. These technologies were designed from the ground up for cell and gene therapy applications. They address the unique requirements for processing and handling different types of "living drugs". In this short presentation, find out how gene therapy companies, and even the PDA itself, utilize COMECER's vial filling automation systems. Explore our latest offerings for cryo-bag filling to accommodate any style cryo-bag. See how COMECER's flexible, modular solutions can be utilized to scale from development all the way to commercial. With 40 years of proven experience in the aseptic isolation and containment industry, COMECER's "Designed-to-Order" GMP Isolators and Automation systems offer a trusted resource for personalized therapy.



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View full company abstract >

VIDEO CHAT: ATTENDEE PERSPECTIVE

Did you know you can meet face to face with Exhibitors via live video chat?

HERE'S HOW:

In the Exhibit Booth, on the left-hand navigation bar, locate the **"Video Chat"** tab. Once you are in that window, hover over the picture of the company representative to see his or her availability.

Click the Video Chat button to pick one of two ways to join the chat. Up to 14 other attendees can join each video chat room.

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Video Chat Representative

Please note that exhibitors will ONLY be available during the times they have listed in their availability. Please hover over the video chat buttons below to view each representative's availability.

When you click the chat buttons below you can pick one of two ways to join the chat. You can use your computer (modern browsers such as the latest versions of Google Chrome, Microsoft Edge, and Firefox are supported) or you can also join with the eventScribe Live app on your mobile device (a great alternative if you have a smartphone).

David Hall
Mon - Tue from 9:30 AM - 4:00 PM EST
Wed from 9:30 AM - 2:45 PM EST

Video Chat
Hover here for availability

Company Details

Contact Info (1 representative)

Resources (6 items)

Video Chat (1 representative)

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VIDEO CHAT OPTION #1

Access the video chat in your browser by clicking the 'Launch' button below to open the video chat in a new window.

Launch

VIDEO CHAT OPTION #2

Access the video chat with the 'eventScribe Live' app.

Download the app from the App Store or the Google Play store and use it to scan the QR code to the right to enter the video chat on your phone or tablet.

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- Pharmaceutical Training
- Training Materials and Services

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CATEGORIES:

- Biotech
- Consulting Services
- Container Closure
- Extractables and Leachables
- Pre-filled Syringe
- Stoppers and Elastomers
- Vaccines
- Vials

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CATEGORIES:

- Analytical Equipment/ Services
- Analytical Labs/Stability
- Biologics (*Blood and Plasma Products*)
- Biopharmaceuticals
- Biotech
- Environmental Monitoring
- Extractables and Leachables
- Microbiology/Environmental Monitoring
- Outsourcing
- Proteins/Peptides

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- Facilities & Engineering
- Process Validation
- QC/QA
- Quality & Regulatory
- Quality Risk Management
- Quality Systems
- Regulatory Affairs
- Technology Transfer
- Validation Services

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CATEGORIES:

- Aseptic Processing
- Biopharmaceuticals
- Biotech
- Cell Therapy
- Clean Room Equipment and Supplies
- Fill/Finish
- Sterilization Sciences

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CATEGORIES:

- Aseptic Processing
- Cell Therapy
- Clean Room Equipment and Supplies
- Facilities and Engineering
- Fill/Finish

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- Disposables
- Drug-Delivery Systems
- Glass Containers/Products
- Pre-filled Syringes
- Quality & Regulatory
- Syringes
- Vials

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CATEGORIES:

- Active Pharmaceutical Ingredient (API)
- Biopharmaceuticals
- Biotech
- Cell Therapy
- Facilities & Engineering
- QC/QA

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The Novatek approach provides the building blocks for a complete quality management solution that can be tailored to any client's needs. Our software can be used as standalone modules or integrated with other modules to form large-scale comprehensive solutions. With 24+ years of successful installations globally, Novatek has developed an extensive base of regulatory knowledge ensuring compliance and peace of mind during audits.

CATEGORIES:

- Environmental Monitoring
- Microbiology/Environmental Monitoring
- QC/QA
- Quality & Regulatory
- Quality Risk Management
- Quality Systems
- Software

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CATEGORIES:

- Analytical Labs/Stability
- Animal Health/Veterinary Products
- Aseptic Processing
- Contract Manufacturing
- Drug-Delivery Systems
- Fill/Finish
- Lyophilization
- Product Development Services
- Sterile Processing
- Technology Transfers

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- Analytical Equipment/Services
- Environmental Monitoring
- Microbiology/Environmental Monitoring
- Validation Services

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CATEGORIES:

- Aseptic Processing
- Biopharmaceuticals
- Microbiology/Environmental Monitoring
- Pharmaceutical Training
- Quality Systems
- Regulatory Affairs
- Sterilization Sciences
- Supply Chain Management

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- Process development
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CATEGORIES:

- Analytical Equipment/ Services
- Container Closure
- Fill/Finish
- Inspection Systems
- Inspection Trends
- Packaging Equipment
- Packaging Science, Container Development
- QC/QA
- Quality & Regulatory
- Syringes

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CATEGORIES:

- Biopharmaceuticals
- Biotech
- Cell Therapy
- Fill/Finish
- QC/QA
- Quality & Regulatory
- Quality Systems

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CATEGORIES:

- Aseptic Processing
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- Inspection Systems
- Packaging Equipment
- Packaging Science, Container Development
- Pre-filled Syringe

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CATEGORIES:

- Auditing and Inspections
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- Quality Risk Management
- Quality Systems
- Regulatory Affairs
- Supply Chain Management

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6060 Spine Rd.
Boulder, CO 80301
Tel: +1 (303) 444-2009
www.suezwatertechnologies.com/sievers

SUEZ, through its Water Technologies & Solutions group and Sievers product line, offers deep expertise in ultrapure water quality monitoring, cleaning validation, and other life science applications. As experts in Total Organic Carbon (TOC), Conductivity, and Bacterial Endotoxins Testing (BET), we will help you optimize your environmental monitoring and cleaning programs while ensuring compliance, accuracy, and maximum efficiency. ISO/IEC 17025 and ISO 17034 accreditations confirm our standards are consistently produced, controlled, and audited. Learn more about Sievers TOC Analyzers and certify reference materials in our virtual booth.

CATEGORIES:

- Analytical Equipment/Services
- Biopharmaceuticals
- Biotech
- Endotoxins
- Environmental Monitoring
- Extractable and Leachables
- Pharmaceutical Water Systems
- Process Automation
- Process Validation
- QC/QAG

TORNADO SPECTRAL SYSTEMS

555 Richmond St. West, Suite 402
Toronto, Ontario M5V 3B1
Canada
Tel: +1 (416) 361-3444 x 140
www.tornado-spectral.com/

Founded in 2013, Tornado Spectral Systems Inc. is a global provider of chemical analysis & measurement systems for Raman spectrometers. Bolstered by its patented High Throughput Virtual Slit (HTVS™) technology, Tornado's HyperFlux Raman spectrometers deliver significantly enhanced photon collection power. The HTVS™ technology allows the best Raman measurement analysis currently achievable anywhere. The superior performance of Tornado's HyperFlux™ PRO Plus Raman spectrometer system allows for more accurate chemical identification, and quantitation even with challenging mixtures and low concentrations, faster measurements of dynamic reactions, and low laser power operation in hazardous environments.

CATEGORIES:

- Analytical Equipment/Services
- Instruments & Controls
- Pharmaceutical Equipment
- Polymers
- Process Automation
- Processing Equipment

COMPANY ABSTRACTS

VALGENESIS, INC.

395 Oyster Point Blvd., Suite 228

South San Francisco, CA 94080

Tel: +1 (510) 445-0505

www.valgenesis.com

ValGenesis is the creator of the first paperless enterprise-wide software platform that serves as a foundation for managing compliance-based validation activities in the life science industry. Compliant with 21 CFR Part 11, Annex 11, GAMP 5 requirements as well as ALCOA+ guidelines, ValGenesis VLMS has become the industry's most trusted electronic validation lifecycle management solution that leverages the power of many years of experience and knowledge supporting Artificial Intelligence (AI), Internet of Things (IoT), Robotics, Advanced Analytics, and Augmented Reality (AR) to help life science companies transform into 'facilities of the future' in their journey towards PHARMA 4.0.

CATEGORIES:

- Biologics (*Blood and Plasma Products*)
- Biopharmaceuticals
- Biotech
- Consulting Services
- Contract Manufacturing
- Facilities & Engineering
- Process Validation

- QC/QA
- Software
- Sterilization Sciences
- Validation Services

VELTEK ASSOCIATES, INC.

15 Lee Blvd.

Malvern, PA 19355

Tel: +1 (610) 644-8335

www.sterile.com

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Innovators for Contamination Control, Veltek Associates, Inc. (VAI®) designs innovative solutions to address the control of particulate and microbial contamination in pharmaceutical, biotechnology, medical device, research & development, healthcare, and lab animal operations worldwide. VAI strives to develop meaningful technical relationships with our clients to ensure that VAI products meet, if not exceed, their unique requirements. VAI's manufacturing and testing operations mirror current GMP/GLP standards. With 40 years of experience our products and services build upon each other to create a "Full Circle Approach" to cleanroom contamination control. Click on "Products & Services" in our virtual booth to learn more.

CATEGORIES:

- Active Pharmaceutical Ingredient (API)
- Aseptic Processing
- Clean Room Equipment and Supplies
- Disposables
- Environmental Monitoring
- Labeling & Coding
- Processing Equipment
- QC/QA
- Sterile Processing
- Sterilization Sciences

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COMPANY CATEGORY LISTING

Active Pharmaceutical Ingredient (API)

IPS-Integrated Project
Services, LLC **12**

Veltek Associates, Inc. **17**

Analytical Equipment/ Services

Boston Analytical **10**

Pace Analytical Life Sciences **13**

PTI Inspection Systems **15**

SUEZ, Water Technologies &
Solutions, Sievers instruments **16**

Tornado Spectral Systems **16**

Analytical Labs/Stability

Boston Analytical **10**

Oakwood Labs **13**

Animal Health/Veterinary Products

Oakwood Labs **13**

Aseptic Processing

Ecolab Life Sciences **11**

G-CON Manufacturing **12**

Oakwood Labs **13**

Parenteral Drug Association **14**

Rommelag USA, Inc. **15**

Veltek Associates, Inc. **17**

Auditing and Inspections

SQA Services, Inc. **16**

Biologics

(Blood and Plasma Products)

Boston Analytical **10**

ValGenesis, Inc. **17**

Biopharmaceuticals

Amgen **9**

Boston Analytical **10**

Ecolab Life Sciences **11**

G-CON Manufacturing **12**

IPS-Integrated Project
Services, LLC **12**

Pace Analytical Life Sciences **13**

Parenteral Drug Association **14**

Regeneron Pharmaceuticals **15**

SUEZ, Water Technologies &
Solutions, Sievers instruments **16**

ValGenesis, Inc. **17**

Biotech

Aptar Pharma **9**

Boston Analytical **10**

Ecolab Life Sciences **11**

IPS-Integrated Project
Services, LLC **12**

Regeneron Pharmaceuticals **15**

SUEZ, Water Technologies &
Solutions, Sievers instruments **16**

ValGenesis, Inc. **17**

Blow/Fill/Seal

Rommelag USA, Inc. **15**

Cell Therapy

Ecolab Life Sciences **11**

IPS-Integrated Project
Services, LLC **12**

Regeneron Pharmaceuticals **15**

Clean Room Equipment and Supplies

Ecolab Life Sciences **11**

G-CON Manufacturing **12**

Veltek Associates, Inc. **17**

Consulting Services

Aptar Pharma **9**

Boston Analytical **10**

CAI **10**

SQA Services, Inc. **16**

ValGenesis, Inc. **17**

COMPANY CATEGORY LISTING

Container Closure

Aptar Pharma **9**
PTI Inspection Systems **15**

Contract Manufacturing

Gerresheimer AG **12**
Oakwood Labs **13**
ValGenesis, Inc. **17**

Contract Research

Boston Analytical **10**

Disposables

Gerresheimer AG **12**
Veltek Associates, Inc. **17**

Drug-Delivery Systems

Gerresheimer AG **12**
Oakwood Labs **13**

Endotoxins

SUEZ, Water Technologies & Solutions, Sievers instruments **16**

Environmental Monitoring

Boston Analytical **10**
Novatek International **13**
Pace Analytical Life Sciences **13**
Parenteral Drug Association **14**
SUEZ, Water Technologies & Solutions, Sievers instruments **16**
Veltek Associates, Inc. **17**

Extractables and Leachables

Aptar Pharma **9**
Boston Analytical **10**
SUEZ, Water Technologies & Solutions, Sievers instruments **16**

Facilities & Engineering

CAI **10**
IPS-Integrated Project Services, LLC **12**
ValGenesis, Inc. **17**

Fill/Finish

Ecolab Life Sciences **11**
Oakwood Labs **13**
PTI Inspection Systems **15**
Regeneron Pharmaceuticals **15**

Glass Containers/Products

Gerresheimer AG **12**

Inspection Systems

PTI Inspection Systems **15**
Rommelag USA, Inc. **15**

Inspection Trends

PTI Inspection Systems **15**

Instruments & Controls

Tornado Spectral Systems **16**

Labeling & Coding

Veltek Associates, Inc. **17**

Lyophilization

Oakwood Labs **13**

Microbiology/ Environmental Monitoring

Boston Analytical **10**
Novatek International **13**
Pace Analytical Life Sciences **13**
Parenteral Drug Association **14**

COMPANY CATEGORY LISTING

Outsourcing

Boston Analytical **10**

Packaging Equipment

PTI Inspection Systems **15**

Rommelag USA, Inc. **15**

Packaging Science, Container Development

PTI Inspection Systems **15**

Rommelag USA, Inc. **15**

Pharmaceutical Equipment

Tornado Spectral Systems **16**

Pharmaceutical Training

Parenteral Drug Association **14**

Pharmaceutical Water Systems

SUEZ, Water Technologies &
Solutions, Sievers instruments **16**

Polymers

Tornado Spectral Systems **16**

Pre-filled Syringes

Aptar Pharma **9**

Gerresheimer AG **12**

Rommelag USA, Inc. **15**

Process Automation

CAI **10**

SUEZ, Water Technologies &
Solutions, Sievers instruments **16**

Tornado Spectral Systems **16**

Process Validation

SUEZ, Water Technologies &
Solutions, Sievers instruments **16**

ValGenesis, Inc. **17**

Processing Equipment

Tornado Spectral Systems **16**

Veltek Associates, Inc. **17**

Product Development Services

Oakwood Labs **13**

Proteins/Peptides

Boston Analytical **10**

QC/QA

CAI **10**

IPS-Integrated Project
Services, LLC **12**

Novatek International **13**

PTI Inspection Systems **15**

Regeneron Pharmaceuticals **15**

SUEZ, Water Technologies &
Solutions, Sievers instruments **16**

ValGenesis, Inc. **17**

Veltek Associates, Inc. **17**

Quality by Design

Gerresheimer AG **12**

Novatek International **13**

PTI Inspection Systems **15**

Regeneron Pharmaceuticals **15**

Quality Risk Management

CAI **10**

Novatek International **13**

SQA Services, Inc. **16**

COMPANY CATEGORY LISTING

Quality Systems

- CAI **10**
- Novatek International **13**
- Parenteral Drug Association **14**
- Regeneron Pharmaceuticals **15**
- SQA Services, Inc. **16**

Regulatory Affairs

- CAI **10**
- Parenteral Drug Association **14**
- SQA Services, Inc. **16**

Software

- Novatek International **13**
- ValGenesis, Inc. **17**

Sterile Processing

- Oakwood Labs **13**
- Veltek Associates, Inc. **17**

Sterilization Sciences

- Ecolab Life Sciences **11**
- Parenteral Drug Association **14**
- Veltek Associates, Inc. **17**

Stoppers and Elastomers

- Aptar Pharma **9**

Supply Chain Management

- Parenteral Drug Association **14**
- SQA Services, Inc. **16**

Syringes

- Aptar Pharma **9**
- Gerresheimer AG **12**
- PTI Inspection Systems **15**
- Rommelag USA Inc. **15**

Technology Transfer

- CAI **10**
- Oakwood Labs **13**

Training Materials and Services

- PDAHealthcare.com **14**

Vaccines

- Aptar Pharma **9**

Validation Services

- CAI **10**
- Pace Analytical Life Sciences **13**
- ValGenesis, Inc. **17**

Vials

- Aptar Pharma **9**
- Gerresheimer AG **12**