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2021 PDA Pharmaceutical Microbiology Conference

EXHIBITOR BUYER'S GUIDE

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4-6 OCTOBER

VIRTUAL EXHIBITION: 4-6 OCTOBER

#PDAmicro

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This Buyer's Guide is designed to help you maximize your virtual 2021 PDA Pharmaceutical Microbiology Conference. 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. While we cannot be together in person, we plan to mark the occasion with the best Microbiology Conference yet! 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.


SCHEDULE-AT-A-GLANCE


All times listed in EDT (UTC -4)


MONDAY, 4 OCTOBER

 10:00 – 11:30
P1: FDA's Current Role in the COVID-19 Vaccines' Development and Emergency use Approvals

 11:45 – 12:15
Exhibit Hall, and Exhibitor Tech Talk Chat with Associates of Cape Cod


 12:15 – 13:45
Concurrent Sessions


 13:45 – 14:15
Exhibit Hall, Poster Chat, Connect & Network (P1, A1, B1), and Exhibitor Tech Talk Chat with Lonza


 14:15 – 15:45
Concurrent Sessions


 15:45 – 16:15
Connect & Network (A2, B2), and Exhibitor Tech Talk Chat with Pall


TUESDAY, 5 OCTOBER


 08:30 – 09:45
Morning Session 1: Understanding Regulatory Expectations and Strategies to Achieve them for Pharmacy Compounding and Virtual Facility Inspections

 10:00 – 11:30
P2: Clean is Not Sterile: A Planetary Science and Planetary Protection Perspective on Cleanroom Microbiology at NASA

 11:30 – 12:00
Exhibit Hall and Connect & Network (Morning Session 1, P2) Exhibitor Tech Talk Chat with TSI


 12:00 – 13:30
Concurrent Sessions


 13:30 – 14:00
Exhibit Hall, Poster Chat, Connect & Network (A3, B3), Exhibitor Tech Talk Chat with Charles River and MilliporeSigma


 14:00 – 15:30
Concurrent Sessions


 15:30 – 16:00
Connect & Network (A4, B4), Exhibitor Tech Talk Chat with Boston Analytical

WEDNESDAY, 6 OCTOBER

 08:30 – 09:45
Morning Session 2: The Criticality of Aseptic Training of Products Quality and Patient Risk

 10:00 – 11:30
P3: Early Career vs Late Career

 11:30 – 12:00
Exhibit Hall and Connect & Network (Morning Session 2, Early Career)

 12:00 – 13:30
Concurrent Sessions

 13:30 – 14:00
Exhibit Hall, Poster Chat, Connect & Network (A5, B5)

TECH TALK INFORMATION

Tech Talks are pre-recorded and made available on our virtual event platform for attendee viewing the week prior to the conference. Representatives from the participating companies will be available for live video chat during the times listed below. Join them face to face.

MONDAY, 4 OCTOBER

11:45 – 12:15

PyroSmart NextGen™ – Recombinant Cascade Reagent (rCR) for BET

Veronika Wills, Technical Services Manager, *Associates of Cape Cod* | vwills@acciusa.com

Another First! Keep Your Method, Make An Impact!

The future of sustainable LAL is here! The launch of Associates of Cape Cod, Inc.'s (ACC) PyroSmart NextGen™ recombinant Cascade Reagent (rCR) marks the introduction of a new sustainable recombinant LAL reagent technology for Bacterial Endotoxin Testing (BET). Veronika will provide an overview of this revolutionary, animal free recombinant cascade reagent, discuss some of the key differences between rCR and rFC based reagents and explain the benefits provided with PyroSmart NextGen™ due to its use of the same LAL cascade as that of traditional LAL reagents. ACC developed PyroSmart NextGen™ to provide a sustainable alternative to traditional naturally sourced LAL reagents, while maintaining your lab procedures, methods, instrumentation and most importantly your results. Come find out more about this exciting new recombinant technology and let us help you meet your sustainability objectives!

13:45 – 14:15

The Compendia Are Ready for Sustainable Pyrogen Detection Methods, Are You?

Allen Burgenson, Global SME – Testing Solutions, *LONZA Walkersville, Inc.* | allen.burgenson@lonza.com

This presentation details the development of pyrogen testing, from rabbits through Limulus amoebocyte lysate (LAL), recombinant Factor C (rFC), and the monocyte activation test (MAT). The latest regulatory acceptance of recombinant methods will be discussed.

15:45 – 16:15

Cut the Cost of Contamination

Kacey Pouliot, Global Product Manager, Microbiology Quality Control Filtration, *PALL* | kacey_pouliot@pall.com

With regulations only becoming more stringent and new biologics being discovered regularly, performing bioburden, sterility and microbial limit testing of raw materials, intermediates or finished products is a crucial step in the dynamic work done by pharmaceutical producers every day.

Cross-contamination during testing can result in false positives requiring costly retests and delaying your products from reaching the market. This presentation will cover topics to help labs prevent contamination while also saving money.

TECH TALK INFORMATION

TUESDAY, 5 OCTOBER

11:30 – 12:00

Considerations for Installing Biofluorescence Particle Counters in an Isolator

Michael Dingle, Product Specialist, TSI | michael.dingle@tsi.com

Changing from using active air samplers and settle plates for viable air testing in isolators to continuous, real-time monitoring with Biofluorescence Particle Counters provides better process understanding with reduced risk, but it also comes with a different set of installation considerations. These considerations must be addressed early in the implementation process and therefore awareness is critical for success.

13:30 – 14:00

Customized Microbial Identification Library for Verification of Product Related Strains

Prasanna Khot, R&D Manager, Charles River | prasanna.khot@crl.com

Microbial isolates are used in the manufacturing process as quality control strains, or during production, or are part of a biotherapeutic product. However, relatively short replication times and horizontal gene transfer may cause the genetic and phenotypic composition of these microbes to be in flux. Sample mix-up due to human error and contamination with other microbes are additional reasons for compromising the predefined integrity of these strains. These factors could have an impact on the reproducibility of the manufacturing process, or functionality of the biotherapeutic product. There is a need for reliable microbial identification approaches to verify the identity of product related strains. A key aspect of this process is to develop custom libraries specifically with product related strains followed by data interpretation to confirm isolate identity. We present a proof-of-concept study to verify identity of individual isolates, and isolates combined in a product mixture, with three identification technologies and related custom libraries, namely, 1) protein profiling by MALDI-TOF mass spectrometry, 2) ribosomal DNA sequence by Sanger Sequencing and, 3) targeted amplicon sequence or Whole Genome Sequence by Next Generation Sequencing. The capabilities and gaps of these technologies will be discussed.

TECH TALK INFORMATION

TUESDAY, 5 OCTOBER

13:30 – 14:00

Robotics and Automation: The Future of QC

Anne Connors, Senior Field Marketing Manager, *MilliporeSigma* | anne.connors@milliporesigma.com

Learn about the possibilities for the future of QC Microbiology. In this presentation, you will learn about how MilliporeSigma is developing digitalized automation and robotic solutions for sampling, testing, and processing of samples across the production environment. This approach to increase product QC by introducing robotic arms and/or stand-alone automated hardware into workflows, flanked by enhanced lab digitalization, carries the additional potential of lowering costs and minimizing the risk posed by human errors.

15:30 – 16:00

Improving Data Integrity in the Microbiology Testing Lab

Yvonne Nyavor, Principal Scientist-Microbiome, *Boston Analytical* | ynyavor@bostonanalytical.com

Microbiology labs perform critical tests that are indispensable to the pharmaceutical industry. Tests such as bioburden, environmental monitoring, endotoxin and sterility testing are all performed in microbiology testing labs and are essential to confirming the safety of drug products. It is therefore extremely important to ensure that the data generated in the microbiology testing lab is of the highest integrity. This presentation will dive into some of the common challenges associated with microbiological data generation and integrity in busy testing labs, and some ways to continuously mitigate these challenges.

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Did you know you can meet with exhibitors via video chat?

Although we are not in person, we can still talk to another human being on the other side of your screen. Navigate through the booths, find the **"Video Chat"** option. Hover over the picture of the video chat representative to see their availability.

You will have two options. Select one and begin to chat. Up to 14 other attendees can join each video chat room.

EXHIBIT WITH PDA NEXT YEAR
PDA
2022 ANNUAL MEETING | DALLAS, TX

Company Details

Contact Info (1 representative)

Resources (6 items)

Video Chat (1 representative)

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 trouble connecting with your computer).

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

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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.

eventScribe Live

COMPANY ABSTRACTS

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Associates of Cape Cod, Inc. (ACC) is a global biopharmaceutical company specializing in endotoxin and glucan detection. ACC was the first company licensed by the FDA to manufacture LAL for use as a quality control test for endotoxin in the pharmaceutical and medical device industry. ACC also operates a contract testing service.



CATEGORIES:

- Biotech
- Endotoxins

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CATEGORIES:

- Aseptic Processing
- Biopharmaceuticals
- Biotech
- Clean Room Equipment and Supplies
- Environmental Monitoring
- Instruments & Controls
- Microbiology/Environmental Monitoring
- Prepared Media

- Process Automation
- Sterile Processing

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CATEGORIES:

- Biopharmaceuticals
- Cell Therapy
- Endotoxins
- Environmental Monitoring
- Microbiology/Environmental Monitoring
- Mycoplasmas
- Prepared Media
- QC/QA
- Rapid Microbio Methods





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COMPANY ABSTRACTS

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Tel: +1 (603) 893-3758
www.bostonanalytical.com

Boston Analytical is a cGMP compliant, FDA/DEA registered, ISO/IEC-17025:2005 accredited pharmaceutical testing laboratory. Boston Analytical provides analytical and microbiological testing services to the Pharmaceutical, Biopharmaceutical and Medical Device industries including Environmental Monitoring services, Sterility testing, Microbial identification and Enumeration, Stability testing & ICH-compliant storage, and Extractables & Leachables studies.

CATEGORIES:

- Analytical Equipment/Services
- Biopharmaceuticals
- Biotech
- Contract Research
- Environmental Monitoring
- Extractables and Leachables
- Microbiology/Environmental Monitoring
- Proteins/Peptides
- Rapid Microbiological Methods
- Validation Services

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As the partner of choice for managing microbial quality control, the Charles River purposely built Microbial Solutions portfolio of Endosafe® endotoxin testing, Accugenix® microbial identification, and Celsis® microbial detection solutions provide clients with the critical, decision driving data necessary to help bring products to market safely and efficiently. Learn more at www.criver.com/microbialsolutions.

CATEGORIES:

- Analytical Equipment/Services
- Analytical Labs/Stability
- Clean Room Equipment and Supplies
- Contract Research
- Endotoxins
- Environmental Monitoring
- Microbiology/Environmental Monitoring
- Process Automation
- Rapid Microbiological Methods

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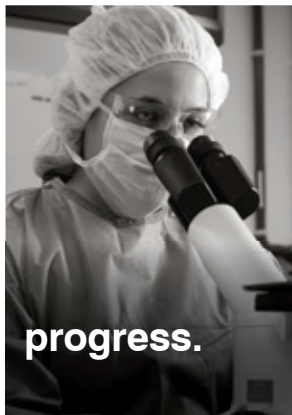
CATEGORIES:

- Chemical Supplier
- Cleanroom Equipment and Supplies



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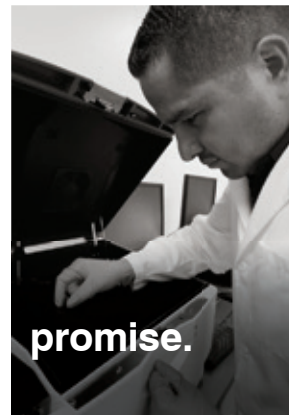
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As the partner of choice for managing microbial quality control, the Charles River purposely built Microbial Solutions portfolio of Endosafe® endotoxin testing, Accugenix® microbial identification, and Celsis® microbial detection solutions provide clients with the critical, decision driving data necessary to help bring products to market safely and efficiently.

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COMPANY ABSTRACTS

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INTERSCIENCE is a family-owned company with a dynamic R&D department that has more than 30 patents filed worldwide. The company has been a key player in microbiology control since 1979. Designer and manufacturer, the company equips laboratories in the food, pharmaceutical, cosmetic and research industries in more than 130 countries, to enable them to provide healthy products for consumers. Our product range covers equipment from sample preparation to bacterial analysis, and includes gravimetric dilutors, lab blenders, peristaltic dispensing pumps, automatic spiral platers, and colony counters.

CATEGORIES:

- Analytical Equipment/Services
- Analytical Labs/Stability
- Biopharmaceuticals
- Biotech
- Environmental Monitoring
- Microbiology/Environmental Monitoring
- Pharmaceutical Equipment
- Process Automation
- QC/QA
- Rapid Microbiological Methods

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CATEGORIES:

- Aseptic Processing
- Biologics (Blood and Plasma Products)
- Biopharmaceuticals
- Biotech
- Endotoxins
- Environmental Monitoring
- Microbiology/Environmental Monitoring
- Process Automation
- QC/QA
- Rapid Microbiological Methods

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CATEGORIES:

- Analytical Equipment/Services
- Instruments and Controls
- Microbiology
- Process Automation
- Processing Equipment



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Lonza offers a complete portfolio of LAL and sustainable pyrogen and endotoxin testing and automation solutions. Our PyroTec® PRO System, powered by WinKQCL® Software, automates the manual tasks associated with endotoxin testing. The MODA® Platform enables paperless environmental, utility and product monitoring and analytics.

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COMPANY ABSTRACTS

MICRON VIEW LIMITED

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MicronView takes advantage of optics and biotechnology to achieve fast, real-time sterile environment monitoring, continuously provides advanced monitoring instruments and consumables for production environment and finished products of food, pharmaceutical and cosmetic industries. Products include BioAerosol Monitoring System, Airborne Particle Counter, BioAerosol Air Sampler and compressed gas, microbial and particle monitoring instruments. Our advanced and comprehensive solutions help environmental monitoring personnel to detect microbial and particulate pollution in realtime, enabling the investigation of pollution sources in less time, and the reliable electronic compressed gas control system makes the detection of microbes and particles in compressed gas easier and more efficient.

CATEGORIES:

- Analytical Equipment/ Services
- Aseptic Processing
- Biotech
- Clean Room Equipment and Supplies
- Environmental Monitoring
- Microbiology/ Environmental Monitoring
- QC/QA
- Quality Systems

- Sterile Processing
- Sterilization Sciences

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CATEGORIES:

- Compliance
- Consulting Services
- Data Integrity
- Environmental Monitoring
- QC/QA
- Quality Metrics
- Quality Risk Management
- Quality Systems
- Software
- Training Materials and Services

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CATEGORIES:

- Analytical Equipment/Services
- Analytical Labs/Stability
- Disposables
- Microbiology/Environmental Monitoring
- Process Automation
- QC/QA
- Syringes

COMPANY ABSTRACTS

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The Parenteral Drug Association (PDA) is the leading global provider of science, technology, and regulatory information. The PDA creates awareness and understanding of important issues facing the pharmaceutical and biopharmaceutical community and delivers high-quality, relevant education to the industry. Since its founding in 1946 as a nonprofit organization, PDA has been committed to developing scientifically sound, practical technical information and expertise to advance pharmaceutical/biopharmaceutical manufacturing science and regulation, so members can better serve patients.

CATEGORIES:

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

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- Speed to market initiatives
- Process development
- Compliance/validation programs
- Automation
- Supply Chain
- Innovation

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CATEGORIES:

- Cell Therapy
- Environmental Monitoring
- Instruments and Controls
- Microbiology
- Pharmaceutical Equipment
- QC/QA
- Rapid Microbio Methods

COMPANY ABSTRACTS

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CATEGORIES:

- Biopharmaceuticals
- Biotech
- Cell Therapy
- Microbiology/Environmental Monitoring
- Mycoplasmas
- Process Validation
- QC/QA
- Quality Risk Management
- Vaccines

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CATEGORIES:

- Aseptic Processing
- Biotech
- Clean Room Equipment and Supplies
- Environmental Monitoring
- Fill/Finish
- Microbiology/Environmental Monitoring
- Pharmaceutical Equipment
- QC/QA

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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

COMPANY CATEGORY LISTING

Active Pharmaceutical Ingredients

Veltek Associates, Inc. 17

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Boston Analytical 11

Charles River Laboratories 11

Interscience Laboratories, Inc. 13

Mettler-Toledo Process Analytics 13

Micron View Limited 15

PALL Corporation 15

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Charles River Laboratories 11

Interscience Laboratories, Inc. 13

PALL Corporation 15

Aseptic Processing

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Micron View Limited 15

Parenteral Drug Association 16

TSI, Inc. 17

Veltek Associates, Inc. 17

Biologics

(Blood and Plasma Products)

LONZA 13

Biopharmaceuticals

BD 9

bioMérieux 9

Boston Analytical 11

Interscience Laboratories, Inc. 13

LONZA 13

Parenteral Drug Association 16

Thermo Fisher Scientific 17

Biotech

Associates of Cape Cod, Inc. 9

BD 9

Boston Analytical 11

Interscience Laboratories, Inc. 13

LONZA 13

Micron View Limited 15

Parenteral Drug Association 16

Thermo Fisher Scientific 17

TSI, Inc. 17

Cell Therapy

bioMérieux 9

Rapid Micro Biosystems Inc. 16

Thermo Fisher Scientific 17

Chemical Supplier

Ecolab 11

Clean Room Equipment and Supplies

BD 9

Charles River Laboratories 11

Ecolab 11

Micron View Limited 15

TSI, Inc. 17

Veltek Associates, Inc. 17

Compliance

Novatek International 15

Consulting Services

Novatek International 15

Contract Research

Boston Analytical 11

Charles River Laboratories 11

Data Integrity

Novatek International 15

COMPANY CATEGORY LISTING

Disposables

PALL Corporation 15
Veltek Associates, Inc. 17

Endotoxins

Associates of Cape Cod, Inc. 9
bioMérieux 9
Charles River Laboratories 11
LONZA 13

Environmental Monitoring

BD 9
bioMérieux 9
Boston Analytical 11
Charles River Laboratories 11
Interscience Laboratories, Inc. 13
LONZA 13
Micron View Limited 15
Novatek International 15
PALL Corporation 15
Rapid Micro Biosystems Inc. 16

Thermo Fisher Scientific 17

TSI, Inc. 17

Veltek Associates, Inc. 17

Extractables and Leachables

Boston Analytical 11

Fill/Finish

TSI, Inc. 17

Instruments & Controls

BD 9
Mettler-Toledo Process Analytics 13
Rapid Micro Biosystems Inc. 16

Labeling and Coding

Veltek Associates, Inc. 17

Microbiology/ Environmental Monitoring

BD 9
bioMérieux 9
Boston Analytical 11
Charles River Laboratories 11
Interscience Laboratories, Inc. 13
LONZA 13
Mettler-Toledo Process Analytics 13
Micron View Limited 15
PALL Corporation 15
Parenteral Drug Association 16
Rapid Micro Biosystems Inc. 16
Thermo Fisher Scientific 17
TSI, Inc. 17

Mycoplasmas

bioMérieux 9
Thermo Fisher Scientific 17

Pharmaceutical Equipment

Interscience Laboratories, Inc. 13
Rapid Micro Biosystems Inc. 16
TSI, Inc. 17

Prepared Media

BD 9
bioMérieux 9

Process Automation

BD 9
Charles River Laboratories 11
Interscience Laboratories, Inc. 13
LONZA 13
Mettler-Toledo Process Analytics 13
PALL Corporation 15

Process Validation

Thermo Fisher Scientific 17

COMPANY CATEGORY LISTING

Processing Equipment

Mettler-Toledo Process Analytics 13

Veltek Associates, Inc. 17

Proteins/Peptides

Boston Analytical 11

QC/QA

bioMérieux 9

Interscience Laboratories, Inc. 13

LONZA 13

Micron View Limited 15

Novatek International 15

PALL Corporation 15

Rapid Micro Biosystems Inc. 16

Thermo Fisher Scientific 17

TSI, Inc. 17

Veltek Associates, Inc. 17

Quality Metrics

Novatek International 15

Quality Risk Management

Novatek International 15

Thermo Fisher Scientific 17

Quality Systems

Micron View Limited 15

Novatek International 15

Parenteral Drug Association 16

Rapid Microbiological Methods

bioMérieux 9

Boston Analytical 11

Charles River Laboratories 11

Interscience Laboratories, Inc. 13

LONZA 13

Rapid Micro Biosystems Inc. 16

Regulatory Affairs

Parenteral Drug Association 16

Software

Novatek International 15

Sterile Processing

BD 9

Micron View Limited 15

Veltek Associates, Inc. 17

Sterilization Sciences

Micron View Limited 15

Parenteral Drug Association 16

Veltek Associates, Inc. 17

Supply Chain Management

Parenteral Drug Association 16

Syringes

PALL Corporation 15

Training Materials and Services

Novatek International 15

Vaccines

Thermo Fisher Scientific 17

Validation Services

Boston Analytical 11