

# 2022 PDA/FDA JOINT REGULATORY CONFERENCE

# EXHIBITOR BUYER'S GUIDE



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**12-14 SEPTEMBER | WASHINGTON, DC**  
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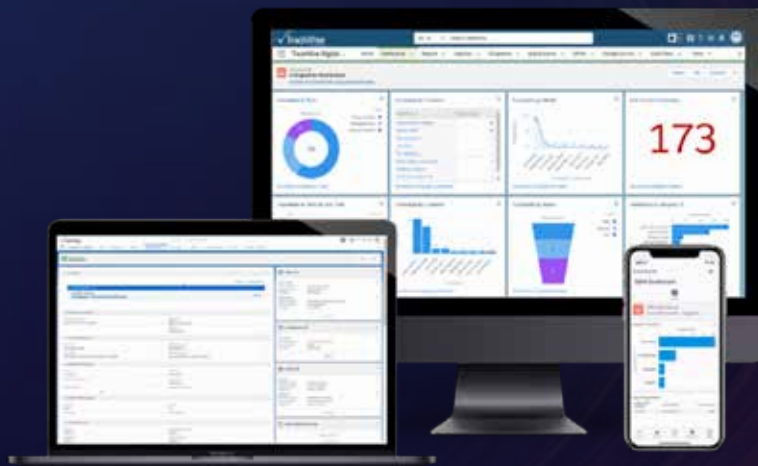
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[spartasystems.com/about-us/](http://spartasystems.com/about-us/)

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# 2022 EXHIBITS COMMITTEE



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**David Hall**  
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This Buyer's Guide is designed to help you maximize your experience at the *2022 PDA/FDA Joint Regulatory Conference*. We are excited to finally be welcoming you back to this meeting in person! Use the **Schedule-at-a-Glance** 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 Exhibit Area and to select those Exhibitors with which you want to connect. The *2022 PDA/FDA Joint Regulatory Conference* will deliver the high-quality content, premier attendee experience, and networking opportunities you have come to expect. Take advantage of the return to face-to-face interaction with thought leaders, peers, vendors, and suppliers at this flagship event.

# SCHEDULE-AT-A-GLANCE

*All times listed in EDT (UTC -4)*

## MONDAY, 12 SEPTEMBER

-  7:00 – 8:30  
**Continental Breakfast**

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-  8:00 – 10:00  
**Plenary 1: Looking to the Future**

---

-  10:00 – 10:45  
**Refreshment Break in Exhibit Area**

---

-  10:45 – 12:15  
**P2: What Does Sustainable Compliance Look Like?**

---

-  12:30 – 13:30  
**Concurrent Interest Group (IG) Sessions**

---

-  13:45 – 15:15  
**Concurrent Sessions**

---

-  15:15 – 16:00  
**Refreshment Break in Exhibit Area**

---

-  16:00 – 17:30  
**Concurrent Sessions**

---

-  17:45 – 18:45  
**Concurrent Interest Group (IG) Sessions**

---

-  19:00 – 22:00  
**Networking Reception**

## TUESDAY, 13 SEPTEMBER

-  7:00 – 8:30  
**Continental Breakfast**

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-  7:15 – 8:15  
**Concurrent Breakfast Sessions**

---

-  8:30 – 10:15  
**P3: Center Office Updates**

---

-  10:15 – 11:00  
**Refreshment Break in Exhibit Area**

---

-  11:00 – 12:45  
**P4: Compliance Office Updates**

---

-  13:00 – 14:00  
**Concurrent Interest Group (IG) Sessions**

---

-  14:15 – 15:45  
**Concurrent Sessions**


---

-  15:45 – 16:30  
**Refreshment Break in Exhibit Area and Passport Drawing | Conclusion of Exhibits**

---

-  16:30 – 18:00  
**Concurrent Sessions**


## WEDNESDAY, 14 SEPTEMBER

-  07:00 – 08:30  
**Continental Breakfast**


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-  07:15 – 08:15  
**Concurrent Breakfast Sessions**


---

-  08:30 – 10:00  
**P5: Current GMP Compliance Trends and Topics**

---

-  10:00 – 10:45  
**Refreshment Break**

---

-  10:45 – 12:15  
**Concurrent Sessions**

\* Schedule subject to change. Latest agenda can be found in the Conference App

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## SILVER SUPPORTERS



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## BRONZE SUPPORTER

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## PASSPORT PARTICIPANTS



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## MEDIA SUPPORTERS



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# COMPANY ABSTRACTS

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Tel : +1 (434) 979-3737

[aftonscientific.com/aseptic-filling-by-anovafill](http://aftonscientific.com/aseptic-filling-by-anovafill) | [information@aftonscientific.com](mailto:information@aftonscientific.com)

Afton Scientific provides cGMP contract sterile filling services of parenteral products. Specializing in small batch clinical and commercial runs with capabilities to batch, sterilize, fill, label, serialize, and package. Afton is the world premiere provider of pre-packaged sterile components (Ready-to-Fill®).

#### CATEGORIES

*Aseptic Processing | Contract Manufacturing | Fill/Finish | Sterile Processing | Vials*

## ASSOCIATES OF CAPE COD, INC.

### Tabletop 15

124 Bernard E. Saint Jean Dr., East Falmouth, MA 02536

Tel: +1 (888) 395-2221

[acciusa.com](http://acciusa.com) | [marketing@acciusa.com](mailto:marketing@acciusa.com)

Associates of Cape Cod, Inc. (ACC), a global biopharmaceutical company specializing in endotoxin and glucan detection was the first company licensed by the FDA to manufacture LAL for use as a quality control BET test. ACC introduced another first when we launched the first BET Recombinant Cascade Reagent, PyroSmart NextGen®.

#### CATEGORIES

*Analytical Labs/Stability | Biopharmaceuticals | Biotech | Consulting Services | Endotoxins*

## AZZUR GROUP

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330 S. Warminster Rd., Suite 341, Hatboro, PA 19040

Tel: +1 (610) 739-2361

[azzur.com](http://azzur.com)

A nationwide network of experts delivering professional services across life sciences, Azzur Group is dedicated to providing clients with quality solutions from Discovery to Delivery™. With more than 250 industry partners, we provide clients with the engineering, validation, IT, training, and laboratory solutions they need to remain innovative and competitive.

#### CATEGORIES

*Auditing and Inspections | Consulting Services | Microbiology/Environmental Monitoring | Quality & Regulatory | Regulatory Affairs*

## CAI

### Tabletop 43

One Park Fletcher, 2601 Fortune Cir. East, Indianapolis, IN 46241

Tel: +1 (317) 271-6082

[cagents.com](http://cagents.com) | [solutions@cagents.com](mailto:solutions@cagents.com)

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#### CATEGORIES

*Quality & Regulatory | Quality Systems | Quality by Design | Validation Services*



# COMPANY ABSTRACTS

## DOT COMPLIANCE, INC.

### Tabletop 60

2375 East Camelback Rd., Suite 600, Phoenix, AZ 85016

Tel: +1 (628) 239-0188

[dotcompliance.com](http://dotcompliance.com) | [hello@dotcompliance.com](mailto:hello@dotcompliance.com)

Dot Compliance offers the industry's first ready-to-use QMS. Dot includes an extensive set of off-the-shelf ready eQMS and compliance pre-configured processes that include full project validation services and product validation packages. Introducing a true eQMS paradigm shift, we offer the industry's most cost-effective quality and compliance management solution available, allowing life science companies to quickly deploy flexible and scalable solutions.

### CATEGORIES

*Quality & Regulatory | Quality Risk Management | Quality Systems | Regulatory Affairs | Software*

## EAGLE ANALYTICAL SERVICES

### Tabletop 55

11111 S. Wilcrest Dr., Houston, TX 77099

Tel: +1 (832) 295-4296

[eagleanalytical.com](http://eagleanalytical.com)

Eagle is an FDA-registered, ISO-certified laboratory providing analytical and microbiological testing for the Healthcare industry since 2004. Our services, including testing, consulting, facility certification, and third-party audits ensure that compounding pharmacies, hospitals, and outsourcing facilities are equipped with the compliance tools to operate in this highly regulated industry.

### CATEGORIES

*Analytical Equipment/Services | Analytical Labs/Stability | Auditing and Inspections | Endotoxins | Rapid Microbiological Methods*

## ECOLAB LIFE SCIENCES

### Tabletop 56

1 Ecolab Pl., St. Paul, MN 55102

Tel: +1 (651) 250-4718

[ecolab.com](http://ecolab.com)

Ecolab Life Sciences is a trusted partner in pharmaceutical manufacturing. We provide innovative contamination control, disinfection, and cleaning solutions for critical manufacturing areas to ensure product quality and safety, while improving operational efficiency.

### CATEGORIES

*Aseptic Processing | Clean Room Equipment and Supplies | Consulting Services*

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### Tabletop 23

303 E. 17th Ave., Suite 10, Denver, CO 80203

Tel: +1 (303) 425-3370

[ellab.com](http://ellab.com)

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### CATEGORIES

*Calibration Services | Instruments and Controls | Process Validation | Software | Validation Services*

# COMPANY ABSTRACTS

## GENESIS PACKAGING TECHNOLOGIES

### Tabletop 18

373 Poplar Rd., Suite 100, Honey Brook, PA 19344

Tel: +1 (610) 458-4900

gen-techno.com

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### CATEGORIES

*Aseptic Processing | Consulting Services | Container Closure | Fill/Finish | Packaging Equipment*

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### PASSPORT PARTICIPANT

### Tabletop 49

Ebano St. I-6, Caparra Hills, Guaynabo, Puerto Rico 00968

Tel: +1 (917) 997-6507

gintegra.com | operationstgg@theintegragroup.com

The Gintegra Group International LLC (TGG) provides a variety of services within the quality and compliance fields. Former FDAers and SMEs for: Remediation activities related to enforcement actions. Inspection readiness plans, mock audits, CAPA verification, batch certification and trainings.

### CATEGORIES

*Consulting Services | Outsourcing | Quality & Regulatory | Quality Risk Management | Quality Systems*

## GXP QUALITY SYSTEMS, LLC

### Tabletop 48

8000 Research Forest Dr., Suite 115-32, The Woodlands, TX 77382

Tel: +1 (713) 882-1987

gxpqslc.com

GXP Quality Systems (GXPQS) provides product lifecycle consulting services (e.g., preclinical, CMC, and clinical development) from R&D to commercialization. We use a Quality Systems approach to establish, improve, or support new or existing processes to enable product development and/or approval. Please visit our website [gxpqslc.com](http://gxpqslc.com) for more information.

### CATEGORIES

*Consulting Services | Contract Research | Quality & Regulatory | Quality Systems | Regulatory Affairs*

## THE HENRICI GROUP

### Tabletop 31

40 Warwick Lake Pkwy., Warwick, NY 10990

Tel: +1 (914) 523-7692

thehenricigroup.com | hg@thehenricigroup.com

Henrici Group (HG) is a boutique New York-based consulting firm that provides strategic and hands-on quality and compliance support to the pharmaceutical industry. HG collaborates with organizational leadership and personnel across multiple functional areas; developing and executing scalable quality initiatives to assure sustainable compliance with regulations, guidance, industry standards, and best practices.

### CATEGORIES

*Auditing and Inspections | Consulting Services | Quality & Regulatory | Quality Risk Management | Training Materials and Services*

# COMPANY ABSTRACTS

## INNERSPACE

### Tabletop 50

Helga-Krismer-Platz 1, Innsbruck, Tyrol 6020, Austria

Tel: +43 664 39667 10

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### CATEGORIES

*Environmental Monitoring | Fill/Finish | Microbiology/Environmental Monitoring | Sterile Processing*

## IWATA LABEL USA INC.

### Tabletop 45

101 Hudson St., 21st Floor, Jersey City, NJ 07302

Tel: +1 (551) 256-0029

[iwatalabel.co.jp/en/](http://iwatalabel.co.jp/en/)

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### CATEGORIES

*Contract Manufacturing | Labeling & Coding | Packaging Equipment*

## KAYE – SUBSIDIARY OF AMPHENOL

### Tabletop 28

Amphenol Thermometrics, 967 Windfall Rd., St. Marys, PA 15857

Tel: +1 (814) 834-9140

[amphenol-sensors.com/en/](http://amphenol-sensors.com/en/) | [kaye-us@amphenol-sensors.com](mailto:kaye-us@amphenol-sensors.com)

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### CATEGORIES

*Instruments & Controls | Pharmaceutical Cold Chain | Pharmaceutical Equipment | Validation Services*

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Tel: +1 (727) 538-4644

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### CATEGORIES

*Consulting Services | Inspection Systems | Packaging Equipment | Software | Visual Inspection of Parenterals*

# COMPANY ABSTRACTS

## LACHMAN CONSULTANTS

### SILVER SUPPORTER

1600 Stewart Ave., Suite 604, Westbury, NJ 11590

Tel: +1 (516) 551-0672

[lachmanconsultants.com](http://lachmanconsultants.com) | [info@lachmanconsultants.com](mailto:info@lachmanconsultants.com)

Through our long-standing mastery of technical and regulatory consultation services, Lachman Consultants serves all areas of FDA-related activities for the Pharmaceutical, Biotechnology, Biologics, Diagnostic, Device & Allied Health Industries.

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#### CATEGORIES

*Active Pharmaceutical Ingredient (API) | Cell Therapy | Combination Products | Consulting Services | Regulatory Affairs*



## LIFE SCIENCE CONNECT

### MEDIA SUPPORTER

5340 Fryling Rd., Suite 100, Erie, PA 16510

Tel: +1 (814) 897-7700

[lifescienceconnect.com](http://lifescienceconnect.com) | [info@lifescienceconnect.com](mailto:info@lifescienceconnect.com)

Life Science Connect's vision is to facilitate connections and foster collaborations in pharmaceutical, biotech, and medical device industries. We promote engagement across the drug development life cycle through our web portals, publications, and events.

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Tel: +1 (434) 293-3081

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Lighthouse Instruments, LLC is a leading global provider of laser-based, non-destructive headspace analysis system. Our product lines include laboratory instruments and fully automated systems for monitoring headspace oxygen, moisture, pressure, and carbon dioxide levels in sealed parenteral containers. Our measurement services business supports product, package, and process development efforts and testing in support of QC stability protocols.

#### CATEGORIES

*Analytical Equipment/Services | Analytical Labs/Stability | Calibration Services | Consulting Services | Container Closure*

## LIVES INTERNATIONAL

### Tabletop 34

250 Cross Farm Ln., Dock #10, York, PA 17406

Tel: +1 (603) 294-3076

[lives-international.com](http://lives-international.com) | [info@lives-international.com](mailto:info@lives-international.com)

Lives International is an industry-leading manufacturer and distributor of thermal validation equipment used in the pharmaceutical/biotech industry. We specialize in real-time wireless temperature, pressure, and humidity data loggers used in a wide range of applications, such as autoclaves, lyophilizers, cryogenic freezers and depyrogenation tunnels.

#### CATEGORIES

*Calibration Services | Cold Chain/Good Transportation Practices | Process Validation | Software | Validation Services*

# COMPANY ABSTRACTS

## LYOPHILIZATION TECHNOLOGY, INC.

### Tabletop 22

30 Indian Dr., Ivyland, PA 18974

Tel: +1 (215) 396-8373

[lyotechnology.com](http://lyotechnology.com) | [inquiry@lyo-t.com](mailto:inquiry@lyo-t.com)

Lyophilization Technology, Inc. is a Contract Development and Manufacturing Organization. The company conducts applied research; provides comprehensive scientific services and technical support, ranging from developing new freeze-dried products and processes and streamlining operations to improving compliance; and manufactures clinical supplies for freeze dried pharmaceuticals, biologics, diagnostics, biopharmaceuticals, and fine chemicals.

### CATEGORIES

*Consulting Services | Contract Manufacturing | Contract Research | Fill/Finish | Lyophilization*

## McFLUSION INC.

### Tabletop 8

2112 Case Pkwy. S., Suite 8, Twinsburg, OH 44087

Tel: +1 (330) 256-0505

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### CATEGORIES

*Consulting Services | Facilities & Engineering | Pharmaceutical Equipment | Software | Washers*

## NOVATEK INTERNATIONAL

### Tabletop 46

2537 Rue Guenette, Saint-Laurent (Montreal), PQ H4R 2E9, Canada

Tel: +1 (514) 668-2835

[ntint.com](http://ntint.com) | [sales@ntint.com](mailto:sales@ntint.com)

Novatek International's mission is to produce regulatory compliant software solutions to the pharmaceutical, biotech and other health-care industries. Our goal is to improve patient safety by producing solutions that reduce the risks associated with pharmaceutical manufacturing and contribute to product quality. Novatek's solutions are modular and process-based providing the building blocks for a complete quality solution.

### CATEGORIES

*Environmental Monitoring | Microbiology/Environmental Monitoring | Quality Systems | Software*

## NSF INTERNATIONAL

### Tabletop 37

789 N. Dixboro Rd., Ann Arbor, MI 48105

Tel: +1 (734) 769-8010

[nsf.org/consulting/health/pharma-biotech](http://nsf.org/consulting/health/pharma-biotech) | [healthsciences@nsf.org](mailto:healthsciences@nsf.org)

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### CATEGORIES

*Auditing and Inspections | Consulting Services | Pharmaceutical Training | Regulatory Affairs | Training Materials and Services*

# COMPANY ABSTRACTS

## PARENTERAL DRUG ASSOCIATION (PDA)

### PASSPORT PARTICIPANT

#### Tabletop 51

4350 East West Hwy., Suite 600, Bethesda, MD 20814

Tel: +1 (301) 656-5900

[pda.org](http://pda.org) | [info@pda.org](mailto:info@pda.org)

The Parenteral Drug Association (PDA) is the leading global provider of science, technology, and regulatory information and education for the pharmaceutical and biopharmaceutical community. Founded in 1946 as a nonprofit organization, PDA is committed to developing scientifically sound, practical technical information and resources to advance science and regulation through the expertise of more than 10,500 members worldwide.

#### CATEGORIES

*Biopharmaceuticals | Biotech | Training Materials and Services*

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### MEDIA SUPPORTER

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[pharmamanufacturing.com](http://pharmamanufacturing.com)

Each issue of *Pharma Manufacturing* magazine reaches more than 25,000 operations and engineering professionals in the pharmaceutical and biotech industries. From our print magazine to our website, and from our webinars to our eBooks and white papers, pharmaceutical and biopharmaceutical professionals are interacting with the information and insights we provide through their medium of choice.

#### CATEGORIES

*Prepared Media*

## PHARMACEUTICAL TECHNOLOGY

### MEDIA SUPPORTER

#### Tabletop 7

485F US Hwy. 1 South, Suite 210, Iselin, NJ 08830

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[pharmtech.com](http://pharmtech.com)

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#### CATEGORIES

*Pharmaceutical Training*

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#### Tabletop 41

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Tel: +1 (404) 680-7070

[pharmalex.com](http://pharmalex.com)

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#### CATEGORIES

*Auditing and Inspections | Biopharmaceuticals | Outsourcing | QC/QA | Quality & Regulatory*

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[pharmtech.com](http://pharmtech.com)

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# COMPANY ABSTRACTS

## PHARMATECH ASSOCIATES

### PASSPORT PARTICIPANT

#### Tabletop 61

22320 Foothill Blvd. #330, Hayward, CA 94541

Tel: +1 (877) 787-0177

pharmatechassociates.com

Pharmatech Associates is a global regulatory consultancy for the life sciences and the consulting arm of USP (US Pharmacopeia). We help manufacturers bring quality products to market and specialize in Product and Process Development, Compliance, Facilities and Capital Projects, and Regulatory Affairs. Our scientists and engineers advise clients from startups to large multinational corporations around the world.

#### CATEGORIES

*Consulting Services | Process Validation | Product Development Services | Quality & Regulatory | Regulatory Affairs*

## PHARMENG TECHNOLOGY, INC.

#### Tabletop 57

1 TW Alexander Dr., Suite 125, Durham, NC 27703

Tel: +1 (919) 413-6796

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A global service provider founded in 1997. We provide subject matter expertise in Commissioning, Qualification, Validation, Quality Systems, Regulatory Affairs, Engineering, Toxicology and Project Management. Our services are provided to a wide range of clients such as pharmaceutical, biotechnology, gene therapy, medical device, and nutraceutical industries.

#### CATEGORIES

*Consulting Services | Process Validation | Training Materials and Services | Validation Services*

## PQE US INC.

#### Tabletop 29

12300 Twinbrook Pkwy., Suite 400, Rockville, MD 20852

Tel: +1 (202) 370-7328

pqegroup.com | Events@pqegroup.com

Since 1998, PQE Group, a consulting company in the pharmaceutical field that is headquartered in Florence, Italy and since 2012 has opened 29 offices worldwide, developing a network of contacts at the international level. PQE has been characterized as Complete Quality Solutions Provider for companies operating in the Life Science field, both nationally and internationally and has more than 1,500 employees.

#### CATEGORIES

*Biopharmaceuticals | Pharmaceutical Equipment | QC/QA | Quality & Regulatory | Regulatory Affairs*

## PSC BIOTECH CORPORATION

#### Tabletop 58

700 Corporate Center Dr., Pomona, CA 91768

Tel: +1 (909) 784-3350

biotech.com | info@biotech.com

PSC Biotech Corporation is a global organization providing life science services and solutions through our professional service consultancy for highly regulated industries, such as pharmaceutical, medical device, and biotechnology. Our PSC Software unit provides inspection/audit management and eQMS through our ACE™ and AuditUtopia™ software.

#### CATEGORIES

*Biotech | Process Validation | Quality & Regulatory | Regulatory Affairs | Software*



# COMPANY ABSTRACTS

## PTI INSPECTION SYSTEMS

### Tabletop 27

8 Skyline Dr., Hawthorne, NY 10532

Tel: +1 (914) 337-2005

[ptiusa.com/home](http://ptiusa.com/home)

PTI is a global leader in package testing equipment. We specialize in non-destructive package testing equipment for high-risk packaging applications. PTI's inspection technologies are deterministic test methods that produce reliable and robust quantitative test result data. We specialize in testing solutions for all parenteral and biologic products including vials, pre-filled syringes, cartridges, auto-injectors, blow-fill-seal and other packaging formats.

#### CATEGORIES

*Calibration Services | Inspection Systems | Inspection Trends | Packaging Equipment | Pre-filled Syringes*

## QUALIO

### SILVER SUPPORTER

#### Tabletop 44

268 Bush St., #3334, San Francisco, CA 94104

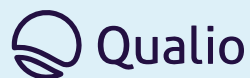
Tel: +1 (855) 203-2010

[qualio.com](http://qualio.com) | [contact@qualio.com](mailto:contact@qualio.com)

Qualio is the first cloud quality management software for all Life Sciences companies. Medical device and pharmaceutical companies need a secure and scalable quality management system with the flexibility to support evolving needs. Qualio meets that challenge by cutting through the complexity to optimize and automate critical quality processes. The remote-first Qualio team is distributed across North America and Europe.

#### CATEGORIES

*QC/QA | Quality & Regulatory | Quality Risk Management | Quality Systems | Regulatory Affairs*



## QUALITY CHEMICAL LABORATORIES, LLC

### Tabletop 39

3400 Enterprise Dr., Wilmington, NC 28405

Tel: +1 (910) 338-5767

[qualitychemlabs.com](http://qualitychemlabs.com)

QCL is committed to the highest levels of scientific quality. Expertise includes analytical development and validation for small and large molecules, stability studies, compendial analysis, microbiology, synthesis, formulation development, and clinical manufacturing. QCL is expanding into new 110,000 square foot facility for sterile fill/finish and lyophilization manufacturing and packaging services.

#### CATEGORIES

*Analytical Labs/Stability | Biopharmaceuticals | Contract Manufacturing | Fill/Finish | Lyophilization*

## QUALITY EXECUTIVE PARTNERS, INC. (VIRTUOSI®)

### Tabletop 26

200 N. Washington St., Suite 320910, Alexandria, VA 22320

Tel: +1 (919) 247-0384

[qualityexecutivepartners.com](http://qualityexecutivepartners.com)

Quality Executive Partners (QxP) is a globally recognized management-consulting firm comprised of leading technical experts and former quality executives within the pharmaceutical industry. QxP's educational platform, Virtuosi®, utilizes 100+ hours of technical courses and 26 interactive VR experiences to teach "How" and "Why" we perform aseptic techniques and behaviors.

#### CATEGORIES

*Aseptic Processing | Cell Therapy | Microbiology/Environmental Monitoring | QC/QA | Training Materials and Services*



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[qualio.com](https://qualio.com)

[View full company abstract >](#)

# COMPANY ABSTRACTS

## REDICA SYSTEMS

### Tabletop 9

6800 Koll Center Pkwy., Suite 120, Pleasanton, CA 94566

Tel: +1 (844) 332-3320

[redica.com](http://redica.com) | [sales@redica.com](mailto:sales@redica.com)

Redica Systems is a data and software company that provides regulatory and quality intelligence to FDA-regulated industries. Today we serve almost 200 pharmaceutical and medical device firms, helping them stay ahead of global regulatory changes, access extensive enforcement and inspection intelligence, monitor supplier risk, and improve team collaboration. More information is available at [redica.com](http://redica.com).

### CATEGORIES

*Quality & Regulatory | Software*

## REES SCIENTIFIC CORP.

### Tabletop 11

1007 Whitehead Rd. Ext, Trenton, NJ 08638

Tel : +1 (609) 530-1055

[reesscientific.com](http://reesscientific.com) | [sales@reesscientific.com](mailto:sales@reesscientific.com)

Since 1982, Rees Scientific has been the most compliant continuous environmental monitoring system in the industry. Our system can monitor the temperature of any cold storage (refrigerators, freezers, ultra-low freezers) from +1300 to -196 °C. We monitor equipment and parameters such as temperature, humidity, light, differential pressure and more. We can help meet regulatory requirements for FDA, GxP & more.

### CATEGORIES

*Clean Room Equipment and Supplies | Cold Chain/Good Transportation Practices | Environmental Monitoring | Instruments & Controls | Validation Services*

## RX-360

### Tabletop 42

21 S. 11th St., Philadelphia, PA 19107

Tel: +1 (888) 218-1164

[rx-360.org](http://rx-360.org) | [info@rx-360.org](mailto:info@rx-360.org)

Rx-360 is a non-profit international pharmaceutical supply chain consortium formed in 2009 to support an industry-wide commitment to ensuring patient safety by enhancing quality and authenticity throughout the supply chain. The organization's mission is to protect patient safety by sharing information and developing processes related to the integrity of the healthcare supply chain and the quality of its materials.

### CATEGORIES

*Auditing and Inspections*

## SMARTSKIN TECHNOLOGIES

### Tabletop 40

354 King St., Suite 195, Fredericton NB E3B 1E3, Canada

Tel : +1 (506) 210-1995

[smartsintech.com](http://smartsintech.com) | [info@smartsintech.com](mailto:info@smartsintech.com)

Smart Skin Technologies provides an industry-leading system to measure damaging forces in parenteral filling and packaging lines. The Quantifeel™ Quality Assurance Platform uses electronic drones to measure pressure and motion on containers at production speeds, helping you understand the effect that operational parameters have on container damage.

### CATEGORIES

*Auditing and Inspections | Cold Chain/Good Transportation Practices | Container Closure | Fill/Finish | Glass Containers/Products*

# COMPANY ABSTRACTS

## SPARTA SYSTEMS, A HONEYWELL COMPANY

### PLATINUM SUPPORTER

#### Tabletop 32

2000 Waterview Dr., Suite 300, Hamilton, NJ 08691

Tel: +1 (609) 807-5100

[spartasystems.com/about-us/](https://spartasystems.com/about-us/) | [SpartaInfo@honeywell.com](mailto:SpartaInfo@honeywell.com)

Sparta Systems, a Honeywell Company, brings leading-edge quality management solutions to regulated industries. With TrackWise® software and the TrackWise Digital® service, Sparta provides enterprise and cloud-based QMS software solutions that help companies go to market faster while minimizing product risks and ensuring compliance. Our products simplify the process of quality management and guide customers toward proactive quality.

#### CATEGORIES

*QC/QA | Quality & Regulatory | Quality Risk Management | Quality Systems | Software*

## Honeywell



## SQA SERVICES, INC.

#### Tabletop 3

425 Via Corta, Suite 203, Palos Verdes Estates, CA 90274

Tel: +1 (800) 333-6180

[sqaservices.com](https://sqaservices.com)

SQA provides global supplier quality solutions to clients in quality-critical industries. Our fully managed programs for audits, engineering, source inspection, remediation, and corrective action management, combined with a global network of quality professionals in more than 50 countries, offers superior visibility and control for any supplier quality initiative.

#### CATEGORIES

*Auditing and Inspections | Quality & Regulatory | Quality Risk Management | Quality Systems | Supply Chain Management*

## STERIS

### PASSPORT PARTICIPANT

#### Tabletop 59

5960 Heisley Rd., Mentor, OH 44060

Tel: +1 (440) 392-7024

[steris.com](https://steris.com)

For more than 100 years, STERIS Corporation has been known as a global leader, trusted partner, and solutions provider in the field of sterilization and contamination control. From formulated chemistries to capital equipment to parts and services, STERIS Life Sciences is Science and Solutions for Life. For more information, visit [sterislifesciences.com](https://sterislifesciences.com)

#### CATEGORIES

*Sterile Processing | Sterilization Sciences*

## THERMO FISHER SCIENTIFIC

#### Tabletop 38

168 Third Ave., Waltham, MA 02451

Tel: +1 (346) 225-3871

[thermofisher.com](https://thermofisher.com)

BIOPRODUCTION: Thermo Fisher Scientific supplies innovative solutions for the world's pharmaceutical and biopharmaceutical industries. With applications that span the drug development process – from drug discovery through large-scale commercial production, we provide a broad range of products and services, including single-use technologies, cell culture media, purification, and analytics. [thermofisher.com/bioproduction](https://thermofisher.com/bioproduction).

#### CATEGORIES

*Active Pharmaceutical Ingredient | Biopharmaceuticals | Biotech | Clinical Trial Materials*

# COMPANY ABSTRACTS

## VALGENESIS, INC.

**BRONZE SUPPORTER**

**PASSPORT PARTICIPANT**

### Tabletop 30

395 Oyster Point Blvd., Ste. 228, South San Francisco, CA 94080

Tel: +1 (510) 445-0505

valgenesis.com | sales@valgenesis.com

ValGenesis is the creator of the industry's leading Validation Lifecycle Management System. This innovative platform handles the entire corporate validation lifecycle and is used by 30 of the top 50 global life science companies. Valgenesis was the first entirely paperless electronic solution for managing validation and remains the most complete solution on the market, covering CSV, CQV, eLogbook, Cleaning etc.

### CATEGORIES

Active Pharmaceutical Ingredient (API) | Consulting Services | Contract Manufacturing | Quality Systems | Validation Services

## VALGENESIS

## VELTEK ASSOCIATES, INC.

### Tabletop 35

15 Lee Blvd., Malvern, PA 19355

Tel: +1 (610) 644-8335

sterile.com | marketing@sterile.com

VAI's manufacturing and testing operations mirror current GMP/GLP standards. With more than 35 years of contamination control experience, our products/ services include a comprehensive line of disinfectants, sporicides, residue removers, process cleaners, quality water, saturated/dry wipes, disposable garments, cleanroom paper, documentation materials, RFID tracking systems, printing systems, viable monitoring, particle counting, cleanroom cart systems, cleaning equipment, consulting, and laboratory services.

### CATEGORIES

Aseptic Processing | Clean Room Equipment and Supplies | Consulting Services | Disposables | Environmental Monitoring

## VEEVA SYSTEMS

### Tabletop 24

4280 Hacienda Dr., Pleasanton, CA 94588

Tel: +1 (925) 452-6500

veeva.com/products/vault-quality/

Veeva is the global leader in cloud software for the life sciences industry. Committed to innovation, product excellence, and customer success, Veeva serves more than 1,000 customers, ranging from the world's largest pharmaceutical companies to emerging biotechs. Veeva powers organizations to manage end-to-end quality processes in one system to drive GxP compliance and operational excellence. For more information, visit veeva.com.

### CATEGORIES

QC/QA | Quality & Regulatory | Quality Systems | Software | Training Materials and Services

# COMPANY CATEGORY LISTING

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## Biopharmaceuticals

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## Biotech

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## Calibration Services

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## Cell Therapy

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## Clean Room Equipment and Supplies

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## Clinical Trial Materials

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## Cold Chain/Good Transportation Practices

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## Combination Products

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## Consulting Services

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## Container Closure

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## Contract Manufacturing

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## Contract Research

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## Disposables

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## Endotoxins

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## Environmental Monitoring

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## Facilities & Engineering

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## Inspection Systems

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## Labeling & Coding

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## Lyophilization

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## Microbiology/ Environmental Monitoring

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## Outsourcing

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## Packaging Equipment

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## Pharmaceutical Equipment

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## Pharmaceutical Training

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## Process Validation

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## Product Development Services

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## Quality by Design

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## Rapid Microbiological Methods

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## Regulatory Affairs

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## Software

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## Sterile Processing

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## Sterilization Sciences

STERIS *Page 19*

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## Supply Chain Management

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## Training Materials and Services

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## Validation Services

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## Vials

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## Visual Inspection of Parenterals

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## Washers

McFlusion Inc. *Page 12*