

# PDA Letter

Regional Edition: Europe

Volume 1 • Issue 3  
November 2020  
[www.pda.org/pdaletter](http://www.pda.org/pdaletter)

## Regulator Develops Remote Inspection Process Due to Pandemic

Vladislav Shestakov, Russian State Institute of Drugs and Good Practices, and Elizabeth Meyers, Amgen

Russia's State Institute of Drugs and Good Practices (SID&GP) recently conducted its first remote GMP inspection of a manufacturing facility for an international pharmaceutical company. The "social distancing" restrictions in place due to Covid-19 limit the number of staff on site, necessitating the novel alternative. This article presents both sides of the experience to provide guidance for both manufacturers and regulators around the globe as they migrate to this new form of inspection (1).

Many regulatory agencies have postponed or completely discontinued GMP inspections due to the COVID-19 pandemic (2-5). Alternative inspection practices have been proposed by both PIC/S and the U.S. FDA, using remote audits as an extraordinary interim measure during Covid-19 quarantines and travel restrictions (6,7).

SID&GP quickly adapted to the current situation in order to avoid medicine shortages, proposing to temporarily conduct remote inspections of foreign pharmaceutical manufacturers. This approach involves a thorough review of submitted documentation and a risk assessment of the manufacturing site. The inspectorate's internal procedures were revised to include a detailed description of the inspection process based on the documents provided by the pharmaceutical manufacturer.

The SID&GP management must provide approval before a remote inspection can be conducted. Their decision to proceed is a risk-based approach, accounting for several factors including results of previous inspections, complexity of the site and criticality of products manufactured at the site (7). For example, if a facility received a GMP certificate from a previous SID&GP inspection, the Agency could allow for a remote inspection that would even permit a new product to be included in a previously granted GMP certificate. If a previous inspection revealed critical findings, however, then a remote repeat inspection will include a thorough review of corrective actions, including

revised documents, validation reports and proof of personnel training. The decision to conduct a remote inspection must be documented in the form of a protocol. Under this new approach, representatives

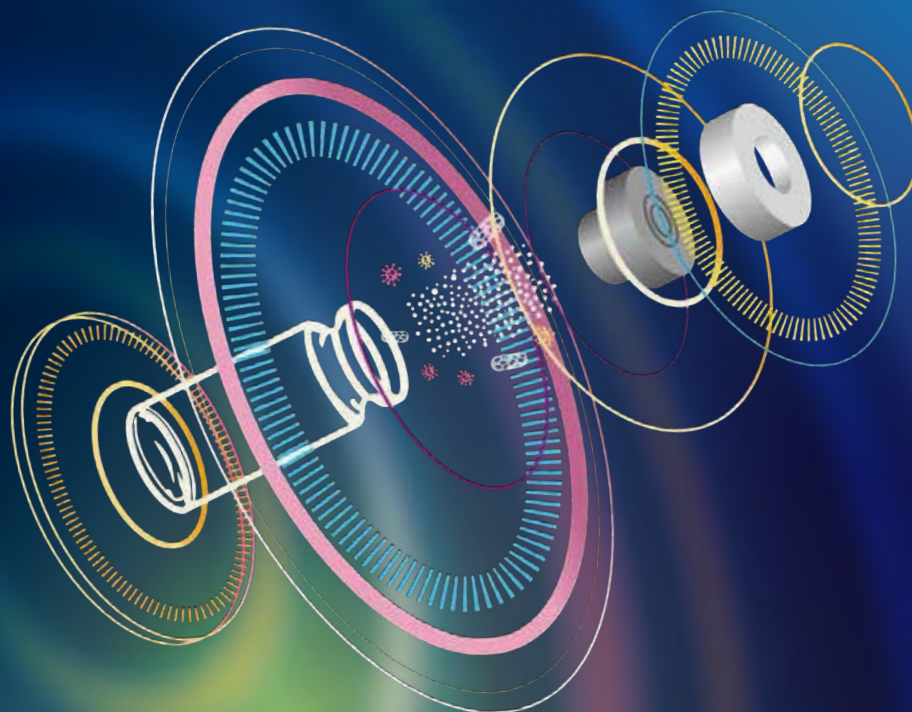
*Continued at bottom of page 9*

Read the authors' 2018 article, "Russian GMP Inspections Present Challenges, Opportunities: Part I," for more information about how the SID&GP was formed and how it performed its first GMP inspection. <https://www.pda.org/pda-letter-portal/home/full-article/russian-gmp-inspections-present-challenges-opportunities-part-i>



# 2021 PDA PARENTERAL PACKAGING CONFERENCE

Parenteral Packaging in a New Era:  
Convergence of Patient, Process and Product Needs



**27-28 APRIL 2021**

**BASEL, SWITZERLAND**

**WORKSHOPS: 26 + 29 APR**

**EXHIBITION: 27-28 APR**

**TRAINING: 29-30 APR**

CONNECTING  
PEOPLE  
**SCIENCE** AND  
REGULATION®

**REGISTER BEFORE 28 FEBRUARY 2021 AND SAVE UP TO €200!**

The PDA Letter is published 6 times per year in print, exclusively for PDA members.

Articles published in the PDA Letter do not represent the official positions of PDA, Inc., but are the opinions of the authors submitting the articles.

Subscriptions are not available.

Articles in the PDA Letter may be reproduced with permission—  
contact the PDA Letter Managing Editor for details. © PDA 2020

## PDA LETTER STAFF

**Senior Director of Publishing**  
Walter Morris  
(301) 656-5900, ext. 148  
morris@pda.org

**Managing Editor**  
Rebecca Stauffer  
stauffer@pda.org

**Graphic Designer**  
Katja Yount  
yount@pda.org

## PDA LETTER EDITORIAL COMMITTEE

Marcia Baroni  
Eli Lilly & Company

Claire Briglia  
Vedere Solutions

Subrata Chakraborty  
Cipla Limited

Walid El Azab  
STERIS

Mirko Gabriele  
Patheon

Robert Guidos  
Corning

David Hubmayr  
CSL Behring

Brian Hawkins, PhD  
Pluristix Inc.

Tamer Helmy, PhD  
Alcon

Zena Kaufman  
ZGK Quality Consulting

Jason Kerr  
Amgen

Gwendolyn Lohr  
Novo Nordisk

Ivy Louis  
Vienni Training and Consulting

Frank Matos  
SOFIE

Aaron Mertens  
STERIS

Ajay Pazhayattil  
Eurofins

Pierre Rousseau  
Acta Biopharma

Siegfried Schmitt, PhD  
PAREXEL Consulting

Andiyanto Sutandar, PhD  
HGP Asia Pte. Ltd.

Cecilia Turoff  
Pfizer

Raji Vathyam  
American Regent

Wendy Zwolenski Lambert  
Novartis

Kelly Waldron  
ValSource

## EXECUTIVE STAFF

Richard Johnson  
President & CEO

David Talmage  
Sr. VP, Education

Glenn Wright  
VP, Scientific & Regulatory Affairs

Jennifer Bell  
VP, Finance

Debbie Goldstein  
VP, Marketing

David Hall  
VP, Sales

Falk Klar, PhD  
VP, PDA Europe

Molly Moir  
VP, Programs & Meetings

Trevor Swan  
Director, Membership & Chapters

## PDA BOARD OF DIRECTORS

### OFFICERS

**Chair** | Jette Christensen, PhD  
Novo Nordisk

**Chair-Elect** | Susan Schniepp  
RCA

**Treasurer** | Melissa Seymour  
Biogen, Inc.

**Secretary** | Emma Ramnarine  
Genentech/Roche

**Imm. Past Chair** | Rebecca Devine, PhD  
Regulatory Consultant

### DIRECTORS

Masahiro Akimoto  
Otsuka Pharmaceutical Factory, Inc.

Barbara Allen  
Eli Lilly and Company

Michael Blackton  
Adaptimmune

Bettine Boltres  
West Pharmaceutical Services

Tia Bush  
Amgen

Ghada Haddad  
Merck & Co.

Joyce Hansen  
Johnson & Johnson

Stephan Krause  
AstraZeneca Biologics

Mary Oates  
Pfizer

Mathias Romacker  
Pfizer (ret.)

Stephan Rönninger  
Amgen

Anil Sawant  
Merck & Co.

## 1 Regulator Develops Remote Inspection Process Due to Pandemic



### People

- 6 Chapter Update | PDA Europe Service Appreciation Award
- 8 Italy Chapter Looks Ahead

### Quality & Regulatory

- 11 Joint Associations' Response Letter on EU Annex 1 Draft

### Voices of PDA

- 5 Foreword PDA Letter European Issue autumn/winter 2020
- 12 Publisher's Message | Get Published And Noticed!

## ADVERTISING SALES

Vice President, Sales  
David Hall  
(301) 656-5900 ext. 160  
hall@pda.org

Articles published in the PDA Letter do not represent the official positions of PDA, Inc., but are the opinions of the authors submitting the articles.

### PDA GLOBAL HEADQUARTERS

4350 East West Hwy., Suite 600  
Bethesda, MD 20814 USA  
Tel: +1 (301) 656-5900  
Fax: +1 (301) 986-0296  
info@pda.org  
www.pda.org

### PDA EUROPE — AM BORSIGTURM 60

Am Borsigturm 60  
13507 Berlin, Germany  
Tel: 49 30 4365508-0  
Fax: +49 30 4365508-66  
info-europe@pda.org

### PDA TRAINING & RESEARCH INSTITUTE

4350 East West Hwy., Suite 150  
Bethesda, MD 20814 USA  
Tel: +1 (301) 656-5900  
Fax: +1 (240) 482-1659  
info-tri@pda.org





[pda.org/2021annual](https://pda.org/2021annual)

# SAVE THE DATE FOR THE 2021 PDA ANNUAL MEETING!



## NEW FORMAT

The **2021 PDA Annual Meeting** promises to have something for everyone.

Dive into exciting interactive sessions and tracks especially designed for **early career professionals, manufacturing leaders, and technical experts/scientists**, all offered in a fully digital format for easy access from anywhere in the world.



## NEW PRICING

No matter what your area of focus, you are sure to come away with tangible, practical solutions to improve your operations and your standing within your company!



## NEW WAYS TO CONNECT

Stay tuned for more information on the intriguing lineup of sessions, speakers, and networking activities.

Register early to take advantage of the most significant discounts!

**For more information and to register, visit**

[pda.org/2021annual](https://pda.org/2021annual)

**PRESENTED VIRTUALLY 15-17 MARCH**

EXHIBITION: 15-17 MARCH  
#PDAannual

CONNECTING  
PEOPLE  
SCIENCE AND  
REGULATION®



# Foreword PDA Letter European Issue autumn/winter 2020

Dear PDA members,

Never before has the saying “it is impossible to predict the future” been more correct than at present. The COVID-19 pandemic teaches us that forecasts and predictions have very limited validity. Although data on COVID-19 is collected worldwide and knowledge is improving, information necessary for an overall understanding is still missing. Important questions regarding the spread of infection, the reasons for differences in severity of the disease or the duration of subsequent immunity cannot be adequately answered yet.

The pharmaceutical industry has a particular importance in the fight against the pandemic. On the one hand, the pharmaceutical industry is working with great commitment on the development, testing, approval and production of vaccines and therapeutic medicines against COVID-19. On the other hand, we must, with our pharmaceutical-technical knowledge, demonstrate compliance with all necessary hygiene regulations in both professional and private life.

Consequently, PDA Europe has converted all conferences into an online format since spring 2020. Training courses suitable for online implementation were held as digital events. The digital conference platform includes exhibitors and posters. Questions to presentations are answered in live Q&A sessions. Text and video chat functions enable the participants to exchange with each other as well as with speakers and exhibitors. Additional discussion groups with subject matter experts allow for in-depth exchange and networking.

PDA Europe will expand these activities in 2021 offering on-site and online participation for all major conferences. This hybrid event format is planned for the first time at the 2021 PDA Parenteral Packaging Conference on 27-28 April 2021 in Basel. It combines the advantages of maximum flexibility with the involvement of speakers and participants from all continents. The global reach of online events allows PDA members to contribute from all over the world in accordance to PDA's motto to connect people, science and regulation.

Other important PDA Europe conferences will be the Quality and Regulations Conference on 18-19 May 2021, the BioManufacturing Conference on 14-15 September 2021 and the Universe of Pre-Filled Syringes and Injection Devices Conference on 5-6 October 2021.

At all events, safety and the protection of health will be top priority. PDA will implement all necessary hygiene precautions at the venues. I am looking forward to an interesting exchange—whether in face-to-face meetings or via digital communication.

In this spirit, I wish you all continued good health and look forward to seeing you all again in 2021.

Sincerely yours,

Falk Klar 🍷



Falk Klar, PhD

## PDA Europe Service Appreciation Award



This award honors special efforts that have contributed to the success of PDA's European activities. **Elisabeth Vachette**, Head of Product Management Bags/Mixing/Tanks, Sartorius Stedim Biotech, is recognized for her involvement in the *2019 PDA Europe Pharma Logistics & Outsourced Operations* conference, among other biopharmaceutical and outsourcing-related PDA activities. She supports the biopharmaceutical industry on a worldwide basis, in particular in process design, validation, training and implementation of single-use fluid management technologies. 🍷



[pda.org/onsite](https://pda.org/onsite)

# Onsite Training

*Customized, Convenient, and Cost Effective*

**PDA can design, develop, and deliver custom training course content, drawing from our extensive network of subject matter experts. We provide:**

- Practical knowledge and skills that improve job performance in a range of important topics
- Engaging instructors with years of industry and agency experience
- The highest quality training, where you want it, when you want it, and at a competitive price

CONNECTING  
PEOPLE  
SCIENCE AND  
REGULATION®

Let us help you succeed with custom solutions and training at your facility or at ours!

Email [info@pda.org](mailto:info@pda.org) to get started today.

# SAVE THE DATE

## for the 2021 Line-up of Conferences

Plan ahead for a year filled with best-in-class content and experiences from PDA. We'll be starting the year mostly online, delivering flexible, accessible, and engaging events. We are optimistically planning to come back together in person in the second half of the year, while continuing to offer a virtual component to these events for those who are still unable to travel. The best of both worlds!



### 2021 PDA Annual Meeting

15-17 MARCH

Presented Virtually

[pda.org/2021annual](https://pda.org/2021annual)



### 2021 PDA Visual Inspection Forum

14-15 APRIL

Presented Virtually

[pda.org/2021visual](https://pda.org/2021visual)



### 2021 PDA Parenteral Packaging Conference

27-28 APRIL

Basel, Switzerland and Online

[pda.org/eu/2021parpack](https://pda.org/eu/2021parpack)



### 2021 PDA Pharmaceutical Microbiology Conference

4-6 OCT.

Washington, DC and Online

[pda.org/2021micro](https://pda.org/2021micro)



### 2021 PDA Universe of Pre-Filled Syringes and Injection Devices Conference

5-6 OCT.

Gothenburg, Sweden and Online

[pda.org/eu/2021ups](https://pda.org/eu/2021ups)



# Italy Chapter Looks Ahead

Angela Molaschi, Chapter President



Il 4 Febbraio 2020 è stato un giorno importante per il PDA IT chapter! Si è infatti svolto a Milano il nostro annual meeting con la partecipazione del Comitato Esecutivo, del Comitato Direttivo e dei membri della nostra associazione.

Dopo un'interessante presentazione sulle nuove linee guida relative ai metodi di sterilizzazione e un aggiornamento sulla revisione dell' Annex 1, il Comitato Esecutivo ha presentato iniziative, eventi e successi del 2019.

Cinque eventi sono stati organizzati nell'anno appena trascorso inclusi training tecnici, conferenze, congressi e un workshop presso Pharmintech (Bologna), una delle più importanti e visitate fiere italiane in ambito farmaceutico. Gli eventi hanno avuto un grande successo con attiva ed entusiasta partecipazione di partecipanti e sponsors! Gli eventi del 2019 sono stati analizzati e discussi nel dettaglio con un focus particolare sui feedback ricevuti dai partecipanti al termine degli eventi stessi e sulle aree di miglioramento: con nostra grande soddisfazione l'analisi fatta ha

mostrato un notevole apprezzamento sia dell'organizzazione sia del valore tecnico e scientifico degli eventi organizzati!

Una sezione della riunione è stata poi dedicata all'analisi della situazione iscritti che si è evidenziata essere stabile ormai da alcuni anni, evidenziando la necessità di attuare nuove iniziative di reclutamento che coinvolgano le tante e importanti realtà farmaceutiche presenti in Italia.

Sempre nel 2019 inoltre PDA IT ha iniziato un'importante collaborazione, di cui siamo molto orgogliosi, con le Università Italiane focalizzata sugli "Young Professionals", di cui siamo molto orgogliosi, e che porterà all'attivazione di un Master Universitario che sarà avviato presso l'Università Statale di Milano nell'Ottobre 2020 e che sarà focalizzato sullo "Sviluppo e Produzione di farmaci sterili".

A chiusura della revisione delle attività del 2019 è stato infine presentato il bilancio del Chapter che ha avuto anche quest'anno una chiusura in positivo.

La seconda parte del pomeriggio è poi stata dedicata ai piani e alle iniziative previste per il 2020. Numerose nuove idee sono state presentate e discusse! Una serie di eventi erano stati programmati tra cui un congresso su "Cleaning and Sterilization methods" un workshop dedicato a "BFS manufacturing", un training tecnico su "Advanced LAL analysis" ed infine un congresso sul "Risk Management".

Purtroppo a causa della situazione di emergenza internazionale legata al COVID-19 e al fine di garantire sicurezza e salute di tutti i partecipanti il Chapter Italiano, in linea con le linee guida PDA, ha deciso di posticipare gli eventi alla seconda parte del 2020 e al 2021. Al fine tuttavia di supportare i propri membri e la comunità farmaceutica anche in questo periodo difficile il Chapter Italiano ha

## PDA Who's Who

**Angela Molaschi**, Technical and Quality Operations Manager, NTC Pharma





## “Young Professionals”, di cui siamo molto orgogliosi, e che porterà all’attivazione di un Master Universitario che sarà avviato presso l’Università Statale di Milano nell’ Ottobre 2020 e che sarà focalizzato sullo “Sviluppo e Produzione di farmaci sterili”



deciso di programmare da Aprile a fine 2020 una serie di webinar su tematiche di grande interesse in ambito parenterale. Il primo webinar, sulla tematica della de-pirogenazione, si è svolto con grande successo il 21 Aprile e una serie di webinar sulla revisione dell’Annex 1 partiranno il 30 Aprile! Il programma dettagliato sarà pubblicato a breve.

In aggiunta all’organizzazione di seminari

ed eventi ad alto valore tecnico/scientifico il PDA IT chapter continuerà nel 2020 la collaborazione con le Università e con le altre associazioni farmaceutiche, supportando e rispettando la missione di PDA e promuovendo il networking e la collaborazione nel campo della Produzione di Farmaci Parenterali!

Grazie ancora al Comitato Esecutivo, al Comitato Direttivo e a tutti i partecipanti

per la grande giornata passata insieme e per tutto il lavoro svolto con passione e dedizione nel 2019!

Non vediamo l’ora di lavorare ancora insieme come sempre...”Connecting People, Science and Regulation®”!

**[Editor’s Note:** This article was [published online](#) in English and Italian on July 7, 2020.] 

*Regulator Develops Remote Inspection Process Due to Pandemic continued from page 1*

of the manufacturing site to be inspected must also provide a written agreement to undergo the remote inspection.

To begin, 10 working days before the inspection, the SID&GP sends the foreign manufacturer a plan, including a list of documents that will be assessed. The manufacturer, usually through its Russian affiliate, forwards the requested documents in an agreed-upon form. Normally, paper copies of documents would be delivered to the SID&GP office by the Russian affiliate representative but, due to restrictions caused by the pandemic, electronic copies are acceptable.

In general, requested information can be sent via email or by any other agreed-upon means. The best way to deliver the documents is to use a secured cloud storage solution restricted to specific participants and made available only during the inspection. Remote inspections require a different level of virtual security as documents are shared in their entirety, whereas during site inspections, the documents are just presented locally to inspectors. Extra time may be required for this should docu-

ments need to be translated, especially if translation of a large document must be completed within a defined timeframe. The inspection team will evaluate these documents and decide if follow-up will be required. If necessary, and agreed upon by both parties, a teleconference can be set up to answer questions. The inspectors may request additional documentation or information to clarify any questions that may have come up during the remote review.

Keep in mind that remote inspections inevitably take a longer than onsite inspections. This can be attributed to several factors, including different time zones and lack of direct real-time contact between inspectors and manufacturing site representatives. When the inspection format is changed to be remote, the inspection routine remains “classic,” that is, the first day of the inspection opens with a presentation in English introducing SID&GP, the inspection team members and the purpose of the inspection. From there, the inspection follows the plan sent to the manufacturing site. On average, a remote inspection can take two to three times longer than an onsite inspection

from start to finish, although there will be some breaks during the remote inspection as information is transferred and considered. Once an inspection has been completed, the team summarizes the potential findings and shares them with the Russian affiliate representative either through email or a close-out meeting via teleconference. The inspection concludes with a report, which is submitted to the applicant within 30 days, the timeframe established by Russian legislation.

### A Site Perspective on Remote Inspections

For the manufacturer, it is very important to thoroughly prepare for a remote inspection. As with traditional onsite inspections, it is crucial to develop an integrated approach and to carefully coordinate work between the company’s Russian affiliate office and the receiving manufacturing site. Quite frequently, international companies’ manufacturing sites produce many product categories, destined for multiple countries. There could be instances where a manufacturing site has misinterpreted requirements of the Russian regulatory dossier, potentially leading to additional

# 2021 PDA THE UNIVERSE OF PRE-FILLED SYRINGES AND INJECTION DEVICES CONFERENCE



questions and findings by inspectors. Prior to an inspection, scheduling a teleconference between the hosting site and the Russian affiliate office is advisable. This will help the site to understand the content of a Regulatory Dossier as well as information within a Form 3, submitted before an inspection. Additionally, a host should have a clear understanding of a product flow beyond the manufacturing site, and a relationship between different legal entities involved in manufacturing, testing, release to market and distribution of a product in Russia.

During a remote inspection, it is necessary to establish an effective work pattern considering the different time zones involved and limited number of employees at the manufacturing facility due to the pandemic. The inspection support group should include not only the site's personnel, but also the Russian affiliate representative and the company's Quality groups to clarify local requirements and answer questions related to specific product flow or Analytical Normative Documents (AND). Russian affiliate representatives play a key role because there is no direct face-to-face contact between inspectors and a hosting site, and the affiliate representatives can serve as a "communication bridge" between a hosting site and inspection team. This representative should establish a positive working relationship with the inspectors. All requests and follow up questions must be submitted in Russian to the affiliate representative, who will then arrange for translation and then forward the questions to a hosting site.

An inspection manager within the hosting site should receive inspection requests and triage them to various Subject Matter Experts. After receiving the corresponding documents and/or records, an inspection manager may have to coordinate legal review and translation of documents. It is important to provide answers in an organized manner, e.g., accompanied by an explanatory letter linking each request to a corresponding response document. It is imperative to establish a mechanism to swiftly translate documents and cover let-

ters. Since these steps can take some time, it is good practice to continue communication with the inspectors, so they know documents are being worked on and not ignored. The Russian affiliate representative can call an inspector to provide timelines and answer any questions.

A recent remote inspection showcases what Russian GMP inspectors might request for further clarification. After initial documents (see box below article) were reviewed by inspectors, follow up questions were asked to clarify which line is used to manufacture product under evaluation along with a request for an executed batch record. Additionally, inspectors requested a list of deviations and complaints related to the product, a list of GMP computerized systems used on the site and a cover page of an audit report for a contract manufacturing site. The initial list contained 31 requested items, followed by an additional 23 questions. Five more queries were received after that. The inspection resulted in two minor findings.

Ultimately, SID&GP considers conducting remote inspections a contingency measure, undertaken only with respect to manufacturing sites subject to reinspection. On-site inspections will be resumed once the COVID-19 pandemic is over. SID&GP does not have a standard approach for all manufacturers requesting a remote GMP inspection. Before electing to conduct a remote inspection, SID&GP would study the drug master file carefully to assess the risk. For example, sterile manufacturing is a high-risk process and, most likely, SID&GP will likely not elect to conduct a remote inspection. From SID&GP's point of view, a remote inspection has a number of limitations. In order to reach an objective decision on a manufacturing site's compliance or noncompliance subject to GMP requirements via remote inspection, SID&GP will apply a comprehensive approach that has been developed during the COVID-19 pandemic.

The COVID-19 pandemic has put manufacturers, affiliates and inspectors in a new and challenging situation where it is in

the public interest to continue to supply medicines while ensuring demonstrated compliance. Thankfully, recent examples of remote inspections show that, with good organization and coordination between the manufacturing site and Russian affiliate representatives, success is realistic and achievable.

## References

1. Federal Law dated 12.04.2010 N 61- $\phi$ 3 (as amended on 04/03/2020) "On Circulation of Medicines" [http://www.consultant.ru/document/cons\\_doc\\_LAW\\_99350/](http://www.consultant.ru/document/cons_doc_LAW_99350/)
2. <https://www.fda.gov/news-events/press-announcements/coronavirus-disease-2019-covid-19-update-foreign-inspections>
3. <https://mhrainspectorate.blog.gov.uk/2020/03/23/mhra-good-practice-gxp-inspections-during-the-covid19-outbreak/>
4. [https://www.sukl.sk/hlavna-stranka/slovenska-verzia/inspekcia/posobnost/vykon-inspekci-pocas-pandemie-covid-19?page\\_id=5339](https://www.sukl.sk/hlavna-stranka/slovenska-verzia/inspekcia/posobnost/vykon-inspekci-pocas-pandemie-covid-19?page_id=5339)
5. [The PIC/S Inspection reliance procedure, PIC/S June 2018](#)
6. MDSAP Transmittal Number: 2020-05, <https://www.fda.gov/media/136441/download>
7. The PIC/S "A Recommended Model on Risk-Based Inspection Planning in GMP Environment," Jan. 1, 2012

## About the Authors

**Vladislav Shestakov** is Director of the Russian State Institute of Drugs and Good Practices (SID&GP) under the Ministry of Industry and Trade of the Russian Federation (MoIT). He is also a certified international WHO GMP inspector.



**Elizabeth Meyers** is a Director of International and Distribution Quality at Amgen. Prior to joining Amgen, she worked as an analytical chemist in both the United States and Russia. For a number of years, she was a member of PDA's Regulatory Affairs and Quality Advisory Board. 



# Joint Associations' Response Letter on EU Annex 1 Draft

Hal Baseman, Valsource, Inc and Annex 1 Response Team Co-Chair

On July 10, 2020, PDA, on behalf of a group of over 10 industry associations, submitted a letter (see box below) to the European Commission and the European Medicines Agency (EMA) to augment the submittal of industry comments which had been requested by EMA for consultation on the February 2020 draft revision to Annex 1.

While the associations submitted their individual sets of more detailed comments, this joint association letter noted where the associations had reached a consensus on several general aspects of the Annex 1 revision.

The letter presented below is significant, because it shows regulators that industry associations with varying membership and objectives can speak with one voice when needed to point out the importance of addressing common concerns.

The latest version of the Annex 1 is one of the most anticipated regulatory guidance documents issued in the past several years. It is expected that the revised Annex 1 will be used worldwide (i.e., not only in Europe) as it is the outcome of the effort of a joint EMA-PIC/S task force. It addresses questions and concerns related to both aseptic process and terminal sterilization of current sterile products and therapies. It will likely be seen and used to help guide companies and regulators to address the challenges of manufacturing new

ATMPs and other advanced therapies, the utilization of innovative technologies and approaches, and the needs for global distribution. It should be appropriate for approaches and innovative technologies that are just now being contemplated and ones that will be developed as we move into the future.

To meet its objectives, the Annex must be clearly written and understood by a wide span of companies manufacturing products in numerous countries throughout the world. It must be based on good scientific and risk management principles. It must allow for, and if possible, encourage, the pursuit and adoption of continuously improved processes and process control

technologies and approaches. It should not be overly prescriptive and become a barrier to companies challenging existing approaches that may not fit modern manufacturing processes.

The associations signing this letter did so to emphasize the importance of the effort and the willingness of the industry to work with regulators to make this a more effective guidance, to better promote its accurate use, and to achieve the common objectives and benefits of all stakeholders, and specifically of the patients.

PDA also submitted its own comments to EMA. 🍷





## Get Published And Noticed!

Why would anyone want to publish an article in *PDA Letter* or their research in *PDA Journal of Pharmaceutical Science and Technology* (JPST)? After all, aren't these restricted access publications that no one but PDA members can read?

These are great questions, and ones we can do a better job answering. In fact, anyone can read both *PDA Letter* and JPST.

Let's start with *PDA Letter*. Ever since we began posting articles online over a decade ago at [www.pda.org/pdaletter](http://www.pda.org/pdaletter), we have included a selection of "open access" articles. Since the pandemic began, all articles have been open access, incidentally, but not before long, we will return to the blend of member-only and open-access content. Nevertheless, nonmembers always have the option of purchasing articles of interest or joining PDA if they want full access.

*PDA Letter* articles are highly visible. Our online readership is strong and growing stronger. From January through June, **over 60,000 pages at the Letter Portal were visited**, a 6% increase over the same period in 2019 and a 36% increase over the same period in 2018. For all of 2019, there were 110,000 page views for the Letter Portal.

We recently updated both the About and Submit pages to better assist readers. We are always seeking articles in the following PDA-critical topic areas:

- Aseptic Processing & Sterilization
- Biopharmaceuticals & Biotechnology
- Manufacturing Science
- Quality & Regulatory
- Supply Chain

PDA's fantastic community of sponsors and technology enablers can publish "Advertorials," which are sponsored articles for a fee. Limited opportunities for sponsored content are available, so be sure to contact Dave Hall, [hall@pda.org](mailto:hall@pda.org) for details.

How about JPST? Well, PDA members might not realize that tens-of-thousands of people have access to JPST every year through PDA membership, well over 100 institutional subscriptions, and article sales. Every PDA member has access to the current volume and immediate past volume of the JPST. Institutional subscriptions provide access to all individuals using registered IP addresses. And anyone can purchase an article! In 2020, we are averaging 120 article sales per month.

All of this contributes to healthy readership of JPST. **Articles published in the last six JPST issues for which metrics are available (Jul/Aug 2019 – May/June 2020) have been accessed, on average, 2,500 times.** These numbers only grow over time, as the JPST archive extends all the way back to 1980.

Since 2019, PDA has worked diligently to provide better author instructions and improve the submission process which are available here: <https://journal.pda.org/content/author-resourcessubmit-paper>, <https://submitjournal.pda.org/>.

So, as you can see, publishing with PDA's two member-benefit publications will help you achieve valuable visibility for your articles and scientific manuscripts.

My question to you is, what are you waiting for? Turn to PDA to get published and noticed! 🍷



Walter Morris, Senior Director of Publishing

[Morris@pda.org](mailto:Morris@pda.org)

[@Walt\\_PDA](https://twitter.com/Walt_PDA)

[www.linkedin.com/in/walter-morris-82191a4](https://www.linkedin.com/in/walter-morris-82191a4)