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# PDA Update in Response to Novel Coronavirus April 24, 2020

R. M. Johnson  
President & CEO




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## Thank you!

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- Thank you to the first responders, all of whom deserve our appreciation and admiration.
  - Health care workers such as doctors and nurses
  - Police officers, emergency medical technicians, firefighters and others who continue to respond to calls and medical emergencies.
- Thank you to the essential workers who continue to provide food, pharmacies, delivers, sanitation.
- Thank you to those working to continue to provide medical products to support not only the fight against COVID-19, but all the essential products that continue to meet the needs of our global community.




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# Current Situation - WHO

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## Coronavirus disease 2019 (COVID-19) Situation Report – 94

Data as received by WHO from national authorities by 10:00 CEST, 23 April 2020



### HIGHLIGHTS

- The Global Outbreak Alert and Response Network (GOARN) has launched a [GOARN COVID-19 Knowledge hubs](#). The hub is designed as a central repository of quality public health information, guidance, tools and webinars which can be accessed freely at any point.
- WHO Director-General Dr. Tedros, in his regular media briefing yesterday, cautioned that “we have a long way to go. This virus will be with us for a long time”. He added that “the world cannot go back to the way things were. There must be a “new normal” – a world that is healthier, safer and better prepared”. His speech can be found [here](#).
- WHO has published guidance “[Addressing Human Rights as Key to the COVID-19 Response](#)”. The guidance document highlights the importance of integrating a human rights-based approach into the COVID-19 response and highlights key considerations in relation to addressing stigma and discrimination, prevention of violence against women, support for vulnerable populations, quarantine and restrictive measures, and shortages of supplies and equipment.
- All available evidence for COVID-19 suggests that SARS-CoV-2 has a zoonotic source. Many researchers have been able to look at the genomic features of SARS-CoV-2 and have found that evidence does not support that SARS-CoV-2 is a laboratory construct. A constructed virus would show a mix of known elements within genomic sequences – this is not the case. For more details, please see ‘subject in focus’.

### SITUATION IN NUMBERS

total (new cases in last 24 hours)

**Globally**  
2 344 792 confirmed (73 657)  
175 694 deaths (6689)

**European Region**  
1 251 458 confirmed (31 972)  
113 336 deaths (2384)

**Region of the Americas**  
957 402 confirmed (82 111)  
47 812 deaths (3038)


**Eastern Mediterranean Region**  
144 450 confirmed (5101)  
8469 deaths (143)

**Western Pacific Region**  
137 902 confirmed (1632)  
5818 deaths (25)


**South-East Asia Region**  
36 039 confirmed (2127)  
1498 deaths (71)

**African Region**  
16 829 confirmed (714)  
748 deaths (28)

**WHO RISK ASSESSMENT**  
Global Level Very High


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# Current Situation - WHO


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## RECOMMENDATIONS AND ADVICE FOR THE PUBLIC

If you are not in an area where COVID-19 is spreading or have not travelled from an area where COVID-19 is spreading or have not been in contact with an infected patient, your risk of infection is low. It is understandable that you may feel anxious about the outbreak. Get the facts from reliable sources to help you accurately determine your risks so that you can take reasonable precautions (see [Frequently Asked Questions](#)). Seek guidance from WHO, your healthcare provider, your national public health authority or your employer for accurate information on COVID-19 and whether COVID-19 is circulating where you live. It is important to be informed of the situation and take appropriate measures to protect yourself and your family (see [Protection measures for everyone](#)).

If you are in an area where there are cases of COVID-19 you need to take the risk of infection seriously. Follow the advice of WHO and guidance issued by national and local health authorities. For most people, COVID-19 infection will cause mild illness however, it can make some people very ill and, in some people, it can be fatal. Older people, and those with pre-existing medical conditions (such as cardiovascular disease, chronic respiratory disease or diabetes) are at risk for severe disease (See [Protection measures for persons who are in or have recently visited \(past 14 days\) areas where COVID-19 is spreading](#)).


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# CDC Data (Apr. 21, 2020)

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## U.S. At A Glance<sup>1,2</sup>

As of April 21, 2020

Total Cases*	Total Deaths*	Total Jurisdictions**
802,583	44,575	55

**In the US and around the world, different governments are preparing phased re-opening mandates.**

\*Total cases includes 3,981 probable cases and total deaths includes 5,862 probable deaths.

\*\*Total jurisdictions includes 50 states, District of Columbia, Guam, the Northern Mariana Islands, Puerto Rico, and the U.S Virgin Islands.



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# WHAT IS PDA DOING TO RESPOND TO THE PANDEMIC?





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## PDA Response

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- For PDA staff, we have suspended all business travel, until further notice.
- **Our Pandemic Preparedness Plan is in effect and we began teleworking for all employees on March 16, 2020.** This is currently extended to the end of April.
- We will continue to monitor the situation and make other announcements, as necessary.
- **We are committed to continue to operate and provide the service** that our members have come to expect from PDA.



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## Introduction

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- **PDA is ramping up our activities in response to the new “normal”:**
  - Member Support
  - Science & Regulatory Activities
  - Virtual Events
  - Virtual Training
  - Continuing Activity



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**Added special section on PDA website this week**

2020 PDA Advanced Therapy Medicinal Products Conference  
June 24-25, 2020 | Washington DC  
[READ MORE](#)

At PDA, our mission is to advance pharmaceutical/biopharmaceutical manufacturing science and regulation so members can better serve patients.

**PDA CORONAVIRUS UPDATES**

New & Noteworthy

- [Announcements](#) | [Events and Training News](#) | [Topic Areas](#) | [Technical Publications](#) | [Global Community](#)

**PDA Universe of Pre-Filled Syringes and Injection Devices**

Do you have significant contributions or case studies to share with other experts?

**PDA Releases First ANSI Standard – Purchasing Controls**

Gain insight into the requirements for purchasing controls throughout the

**PDA Strategic Plan 2020-2026**

Find out about the Plan's objectives, the development process, and download a copy today.

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**PDA** Parenteral Drug Association  
Connecting People, Science and Regulation®

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**PDA Coronavirus Updates**

[PDA Coronavirus Statement/Updates](#) | [PDA Coronavirus Task Force](#) | [Coronavirus Newsfeed](#)

**PDA Statement Regarding COVID-19**

*Last updated: April 27, 2020*

PDA considers safety and health of event attendees as a subject of utmost importance. This is relevant as attendees from various countries, regions, and continents will come to PDA events. The coronavirus Our sympathies are with those affected around the world.

PDA is committed to maintaining opportunities for volunteers and individuals from the pharmaceutical industry to meet, wherever we can do so. PDA relies on experts in that field, from global bodies like national and local health authorities where we are running events, to provide appropriate guidance.

PDA has implemented a set of measures to protect participants and staff from potential risks related to COVID-19 as best as possible. This includes a close and regular monitoring of the situation, adherer authorities and official travel warnings, possibilities of remote presentations, and precautions being implemented at our venues.



For PDA staff, we are suspending all business travel, until further notice. Our Pandemic Preparedness Plan is in effect, and began teleworking for all US and EU employees on March 16, 2020. We will cont make other announcements, as necessary.

We have suspended the expiration of existing memberships until the end of June, 2020. As of now, all members will continue to enjoy the benefits of membership even if you are unable to pay due to the pandemic.

Be assured that we will continue to operate and provide the service that our members have come to expect from PDA.

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## Member Support

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- **We have suspended the expiration of existing memberships until the end of June 2020.** As of now, all members will continue to enjoy the benefits of membership even if you are unable to pay due to the impact of the corona virus pandemic.
- PDA has placed our PDA Letter in the “open’ to allow members and non-members to access it for the time being
- PDA has placed our PDA Journal in the “open’ to allow members and non-members to access it for the time being





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## Science & Regulatory Activities

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### Coronavirus Pandemic Response Task Force

- **Task Force Leader:** Anil Sawant, PhD,
  - Sr. VP of Global Quality Compliance, Merck & Co., Member of PDA Board of Director
- **Current Status:** Task force has formed and has started its work
- **Task Force Focus:** This Task Force is focusing on actions that are recommended to ensure the continued manufacturing and supply of product during an active outbreak.
  - The task force will develop suggested actions on GMP processes and controls that proactively take into account the potential for viral outbreaks as it relates to manufacturing to ensure continued as well as increased supply demand for pharmaceutical products.
  - The task force will provide comments to new and existing regulatory guidance as well as identify where new guidance may be needed to ensure that the enormous surges in the demand for pharmaceutical products that occur under these circumstance can be managed effectively to the greatest extent possible.




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
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## Coronavirus Pandemic Response Task Force

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**Deliverables And Status:**

- Industry Survey on Impact of Coronavirus to Manufacturing Operations (In-process, survey to close this week with readout expected by the first week in May)
- Initial Publication on Coronavirus covering the virus and specific areas that should be considered related to manufacturing operations (In-process, initial draft completed)
- Webinars specific to consideration for manufacturing and supply chain operations (Planning and scheduling initiated)
- Commenting on new and existing regulatory guidance as well as proposing where new guidance may be needed. (Not yet initiated)
- Development of a PDA Points to Consider document focused on preparing for and responding to a pandemic in regards to manufacturing and supply chain operations (Not yet initiated)


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## PDA Statement Regarding COVID-19

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### PDA EVENTS

- **2020 PDA Annual Meeting** in Raleigh, NC, was rescheduled to July 20-22, 2020. We are moving to a **Virtual Only** meeting.
- The **Visual Inspection Forum (EU)** planned for April is being moved to October.
- **Interphex** moved from April to July
- We are repositioning the **ATMP Conference** in June (US & EU) to Virtual Only.
- We are repositioning the **Virus Conference** in June (EU) to Virtual Only.
- We are repositioning the **Quality & Regulatory Conference** in June (EU) to Virtual Only.
- All Training in Europe and US has been cancelled or rescheduled through May.
  - We have courses available on-line, either as computer-based training or as live virtual training.
- We are currently planning to resume in person events in September, with Virtual options.


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  **Virtual Events –US Time Zone** pda.org

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**PDA Update on Coronavirus Response**  
🕒 Apr 24, 2020 📍 Online, Webinar [REGISTER NOW](#)

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**PDA Webinar: Applying the Lifecycle Approach to Develop a Control Strategy for ATMPs (Part 1 of 2)**  
🕒 Jun 02, 2020 📍 Online [REGISTER NOW](#)

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**PDA Webinar: Applying the Lifecycle Approach to Develop a Control Strategy for ATMPs (Part 2 of 2)**  
🕒 Jun 04, 2020 📍 Online [REGISTER NOW](#)

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**PDA Webinar: Coronavirus and ATMPs - Addressing Pandemic through Innovation**  
🕒 Jun 09, 2020 📍 Online [REGISTER NOW](#)

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  **Virtual Events –US Time Zone** pda.org

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**PDA Webinar: Enhancing Flexibility and Compliance for ATMP Manufacturing Facilities**  
🕒 Jun 11, 2020 📍 Online [REGISTER NOW](#)

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**PDA Webinar: Cell Therapy Process Development Challenges**  
🕒 Jun 16, 2020 📍 Online [REGISTER NOW](#)

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**PDA Webinar: Advancing ATMPs in a Dynamic Regulatory Environment**  
🕒 Jun 18, 2020 📍 Online [REGISTER NOW](#)

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**PDA Webinar: The Need for Speed: A Risk-Based Approach to Optimize Time and Patient Safety**  
🕒 Jun 23, 2020 📍 Online [REGISTER NOW](#)

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## Virtual Events –US Time Zone

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PDA Webinar: Recent Breakthroughs in Gene Therapy Using AAV Delivered DNA  
🕒 Jun 25, 2020 📍 Online [REGISTER NOW](#)

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PDA Webinar: Regulatory Challenges, Perspectives, and Convergence to Progress ATMPs  
🕒 Jun 30, 2020 📍 Online [REGISTER NOW](#)

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2020 PDA Pharmaceutical Manufacturing Data Science Workshop  
🕒 Jul 23, 2020 📍 Online [COMING SOON](#)

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## Virtual Events – EU Time zone

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PDA Europe Virtual Conference - Quality and Regulations  
🕒 Jun 09 - Jun 11, 2020 📍 Berlin, Europe [REGISTER NOW](#)

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PDA Europe Virtual Conference - Virus Forum  
🕒 Jun 22 - Jun 23, 2020 📍 Berlin, Europe [REGISTER NOW](#)


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PDA Europe Virtual Conference - Advanced Therapy Medicinal Products  
🕒 Jun 24 - Jun 25, 2020 📍 Berlin, Europe [REGISTER NOW](#)

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 **Virtual Training** pda.org

Event Type  Event Region  Topic Area  [FILTER](#)

ACTIVE FILTERS: VIRTUAL ✕ CLEAR ALL

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On Demand eLearning - PDA 592 ICH Q7 GMP for APIs  
🕒 Jan 01 - Dec 31, 2020 📍 Online [REGISTER NOW](#)


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On Demand eLearning - PDA 578 Technical Report No. 79: Particulate Matter Control in Difficult to Inspect Parenterals  
🕒 Jan 01 - Dec 31, 2020 📍 Online [REGISTER NOW](#)


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On Demand Webinar - PDA 597 Quality Culture: Why Assessment is Important  
🕒 Jan 01 - Dec 31, 2020 📍 Online [REGISTER NOW](#)

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 **Virtual Training (cont.)** pda.org

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
Live eLearning - PDA 739 GMPs for Compounders  
🕒 Jun 02, 2020 📍 Online [REGISTER NOW](#)

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# Other News from PDA

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- Recognizing the growing importance and impact of cell and gene therapy products, the Board resolved to create an **Advanced Therapy Medicinal Products Advisory Board**. This new advisory board will oversee PDA projects and Interest groups in these areas as well as provide guidance to PDA in the development of events, trainings, and technical publications to assist companies developing gene therapy medicinal products, somatic cell therapy products, and tissue engineered products. Michael Blackton, VP Global Quality, Adaptimmune, LLC, and Stephan Krause, PhD, Head of Product Quality, AstraZeneca Biologics, have been appointed to form and lead the new advisory board.
- PDA also named new members to its Board of Directors, as Glenn Wright left the all-volunteer body to join PDA staff as the Vice President of Scientific and Regulatory affairs in March. **Melissa Seymour, Biogen, Inc., assumed the role of Treasurer; Emma Ramnarine, Roche Pharma, assumed the role of Secretary, and Stephan Roenninger, Amgen** joined as a Director.
- For more information about PDA, its volunteer boards and committees, and leadership, go to PDA's website.


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# Continuing Activities

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04/17/2020

**PDA Announces Availability of ANSI/PDA Standard 001-2020 on Purchasing Controls**

Bethesda, Md. - The Parenteral Drug Association (PDA) today announced the availability of ANSI/PDA Standard 001-2020, Enhanced Purchasing Controls to Support the Bio-Pharmaceutical, Pharmaceutical, Medical Devices, and Combination Products Industries, which was approved by the ANSI Board of Standards Review on March 13, 2020.

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04/07/2020

**Parenteral Drug Association Announces its 2020 - 2026 Strategic Plan**

Bethesda, Md. - The Parenteral Drug Association, Inc. (PDA) today announced the availability of its 2020 - 2026 Strategic Plan, which was developed to assist PDA in achieving its vision to be the premier global leader in advancing bio/pharmaceutical manufacturing, science, technology, and regulation to enable members to better serve patients. The plan was developed by PDA's Strategic Planning Committee at the direction of the PDA Board of Directors.

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03/27/2020

**Parenteral Drug Association Announces Measures to Support Pharma/Biopharma Industries during Covid-19 Pandemic**

Bethesda, Md. - The Parenteral Drug Association (PDA) announced that it is suspending membership expirations retroactively to March 1 and continuing until the end of June. All members will continue to enjoy the benefits of membership, even if you are unable to pay due to the impact of the corona virus pandemic.



**PDA Standard 001-2020**  
Enhanced Purchasing Controls to Support the Bio-Pharmaceutical, Pharmaceutical, Medical Devices and Combination Products Industries




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 **Questions** pda.org

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 **Contact Information** pda.org

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