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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 hub. 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 '<u>Addressine Human Rights as Key to the COVID-19</u> <u>Response</u>'. 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 forces."

SITUATION IN NUMBERS

#### Globally 2 544 792 confirmed (73 657)

European Region 1 251 458 confirmed (31 972)

Region of the Americas 957 402 confirmed (82 111)

Eastern Mediterranean Region 144 450 confirmed (5101)

Western Pacific Region 137 902 confirmed (1632)

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

African Region 16 829 confirmed (714)

WHO RISK ASSESSMENT



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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 <a href="Frequently Asked Questions">Frequently Asked Questions</a>). 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 <a href="Protection measures for everyone">Protection measures for everyone</a>).

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 <u>Protection measures for persons who are in or have recently visited (past 14 days) areas where COVID-19 is spreading).</u>



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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 reopening mandates.

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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<sup>\*</sup>Total cases includes 3,981 probable cases and total deaths includes 5,862 probable deaths.

<sup>\*\*</sup>Total jurisdictions includes 50 states, District of Columbia, Guam, the Northern Mariana Islands,



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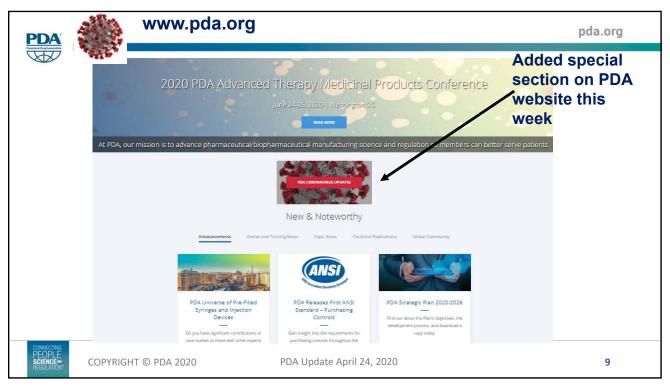
- PDA is ramping up our activities in response to the new "normal":
  - Member Support
  - Science & Regulatory Activities
  - Virtual Events
  - Virtual Training
  - Continuing Activity



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# 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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# **Coronavirus Pandemic Response Task**

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#### olivorables

# 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 were 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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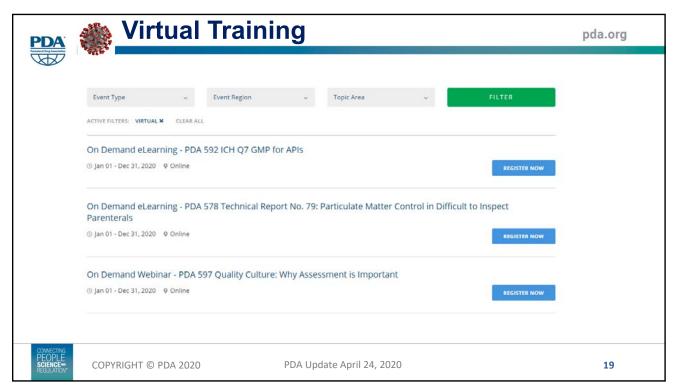
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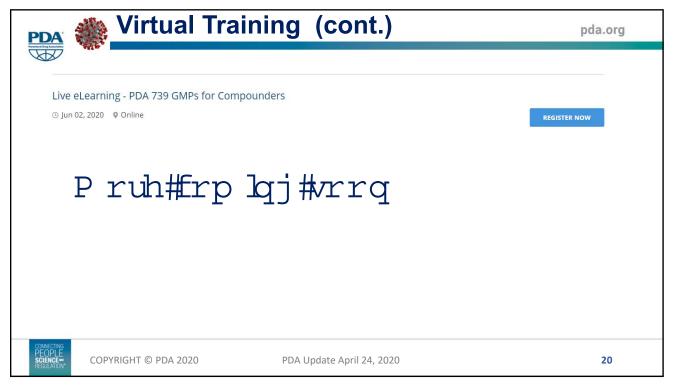














# Other News from PDA

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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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PDA Standard 001-2020 Enhanced Purchasing Controls to

apport the Bio-Pharmaceutical,

Pharmaceutical, Medical Devices and Combination Products

Industries

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.

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.

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.



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