



ANNUAL REPORT

2020



PDA 2020 Events

PDA U.S.

34 Events

Virtual

Virtual Events (conferences and workshops)	12
Webinars	22

88 Training Courses

In-Person

Bethesda, MD	8	San Diego, CA	1
Indianapolis, IN	1		

Virtual

Online	51	Online – Onsite	8
Online – APAC	5	Online – Webinar	1
Online – India	13		

PDA Europe

19 Events

In-Person

Conference	1	Training Courses	5
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Virtual

Conferences	8	Training Courses	5
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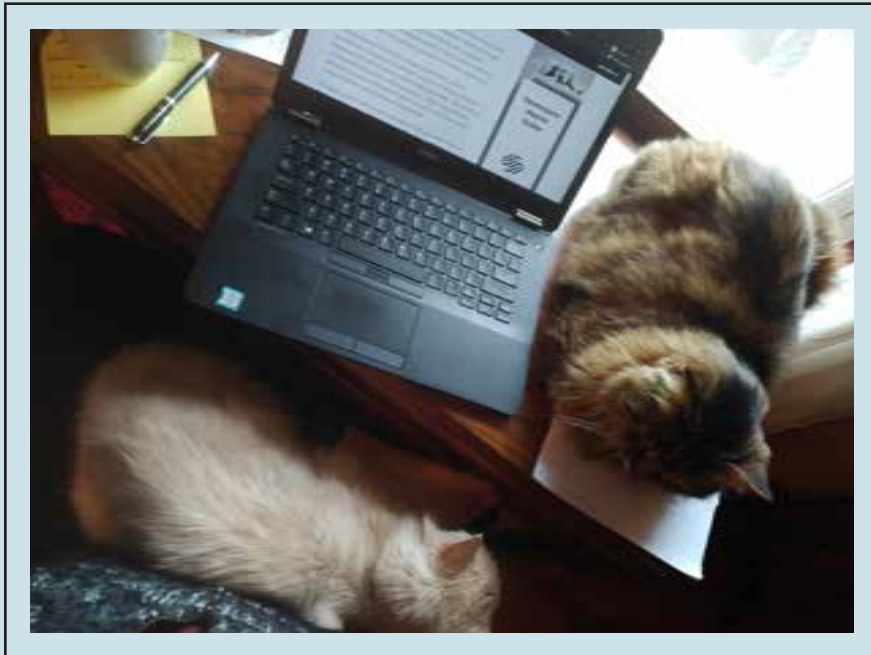
PDA Asia Pacific

2 Events

Virtual

Conferences	2
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Chair's Message

What has the year 2021 in store for us?

First and foremost, I wish you all a Happy New Year. I sincerely hope that 2021 will bring you happiness, good health, and harmony.

2020 was a very unusual year. The COVID-19 pandemic changed our world and our way of living. We had to isolate ourselves, wear face masks outside the classified areas and our homes, and learn to work in different ways. Whether we work for a pharmaceutical company, a vendor, academia, a regulatory agency, or as a consultant, we have all been impacted.

Even the PDA organization has been forced to find a new way of working. For sure, 2020 was a challenging year, but we gained many good learnings that we can use to benefit members.

Sudden Move to Virtual Events

Last year, our Annual Meeting was the first meeting/conference that we had to change into a virtual event. Since then, we have held several virtual meetings and continuously improved the digital setup. The PDA staff has worked very hard on improving the quality of our digital solutions, and we are now in a position where we can proudly say that we provide participants with very high-quality virtual conferences and training sessions. We will, of course, still focus on refining and delivering the best possible virtual conference and training setups.

Event Calendar 2021: Virtual and Hybrid

For your kind information, we will continue our signature conferences--the Annual Meeting, Quality and Regulation Conference, PDA/FDA Joint Regulatory Conference, Pharmaceutical Microbiology Conference, and Universe of Pre-Filled Syringes and Injection Devices Conference.

Conferences on new topics will be held, too, like the Robotics and Automation Conference. Please visit our event calendar and learn more about them.

We now expect that traveling across borders will remain restricted, at least during the first half of 2021, so our conferences will continue to be run solely on a virtual platform. When it traveling is safe again, we will offer both face-to-face and virtual events, often in a hybrid shape of the two. 2020 has shown us that virtual meetings provide some benefits, for example, that you do not need to travel and that our virtual conferences allow you the opportunity to watch the recorded video presentations when it fits into your time zone. However, we are painfully aware that you miss meeting face to face, networking and building new relationships, shaking hands, or sometimes even giving each other a hug.

Finally, we will continue our wide range of e-learning events and webinars.

PDA Advisory Boards

In 2021 our advisory boards, SAB, BioAB, ATMP, and RAQAB will, as usual, monitor the current hot topics that impact our members, and will provide input to PDA activities.

The advisory boards ensure that the task forces will deliver high-quality documents that include technical reports, "Points to Consider" papers, and standards. You can look forward to receiving interesting and up-to-date science- and risk-based technical information — just stay tuned.

COVID-19 Task Force

In 2020, our COVID-19 task force offered, among other things, a series of webinars on virology and coronaviruses, remote inspections, inspection preparation, FDA guidance on COVID-19, and modular manufacturing to enhance/upscale capacity.



Chair
Jette Christensen, PhD
Novo Nordisk



Chair-Elect
Sue Schniepp
RCA



Treasurer
Melissa Seymour
Bogen



Secretary
Emma Rammnarine
Genentech/Roche



Immediate Past Chair
Rebecca Devine, PhD
Regulatory Consultant

Board of Directors



Masahiro Akimoto
Otsuka Pharmaceutical
Factory, Inc.



Barbara M. Allen,
PhD
Eli Lilly and Company



Michael Blackton
Adaptimmune



Bettine Boltres, PhD
West Pharmaceutical
Services

In 2021, the task force will provide you with more valuable information on how to handle the pandemic in the pharmaceutical world. Please remember to check our website in order not to miss any important webinars.

Supporting the PDA Vision and Mission

As you can see from the above examples, PDA will have plenty of deliverables in store for you in 2021. These deliverables are only possible due to our very competent staff who successfully plan all the offerings and due to our active PDA members. I would like to thank all the PDA member volunteers who are willing to share their vast knowledge and put a lot of time and effort into these tasks. Your strong commitment makes the PDA able to fulfil our vision and mission.

Vision

- To be the premier global leader in advancing pharmaceutical and biopharmaceutical manufacturing science, technology and regulation, enabling members to better serve patients

Mission

To maximize product quality, availability, and value by connecting people, science and regulation within the pharmaceutical and biopharmaceutical community as:

- The preferred choice for professionals who seek to acquire specialized, innovative skills and knowledge enhancing their professional development
- The premier education partner for professionals in academia, industry and government for the advancement of manufacturing, quality and regulatory science
- An organization that aligns its practices and resources to support its core values of science-based approach, integrity and inclusion



Tia Bush
Amgen



Ghada Haddad
Merck & Co.



Joyce Hansen
Johnson & Johnson



Stephan Krause, PhD
AstraZeneca Biologics



Mary Oates, PhD
Pfizer



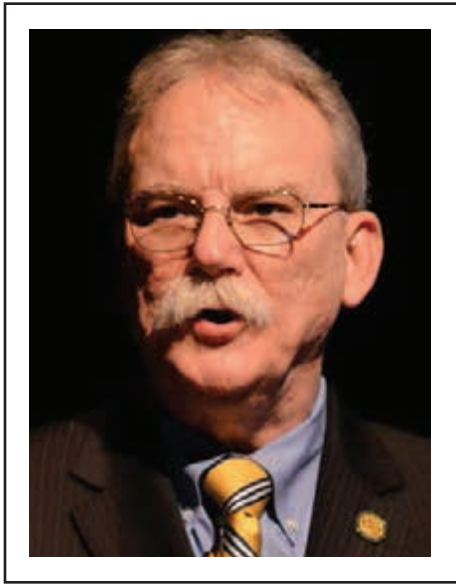
Mathias Romacker
Pfizer (ret.)



Stephan Rönninger
Amgen



Anil Sawant, PhD
Merck & Co., Inc



President's Message

President's Message: A Year Like No Other

We finally saw the end of a year like no other—2020. The global coronavirus pandemic challenged each of us, including our organizations, governments, and families.

First and foremost, we should consider the impact this has had on so many lives around the world. The health impact has been staggering, and it is hard to envision that as of January 12, 2021 almost 2 million people have died, and more than 91 million have been infected. In addition to the terrible health impacts, the control measures that are continuing to be implemented have affected many more people's livelihood and social activity.

But 2020 also saw our industry respond to the crisis in dramatic ways: continuing to supply critical medical products; rapidly developing diagnostics and treatments; and developing vaccines in an unprecedented short time. All our members, in ways large and small, contributed to this effort.

Here at PDA, we have been similarly called upon to deal with this crisis. We rapidly shifted our staff to remote working. We rescheduled, canceled, and restructured to virtual, dozens of conferences, workshops, and training courses. Through it all, we have striven to maintain the support for you, our members. Through your efforts, we continued to bring valuable information and content to members and non-members worldwide.

In 2020 we hosted more than 100 events, from conferences and workshops to webinars and training courses. Our team worked hard to rapidly assess platforms and implement virtual events. Our science and regulatory efforts yielded our first ANSI standard, 12 other technical publications, and 9 regulatory comments. We published translation of several technical reports in Japanese, Chinese, and Spanish. We launched Europe and Asian editions of the *PDA Letter*.

As we look forward to 2021, we know that the pandemic situation continues to have a major impact. Nonetheless we expect an even busier year, with global conferences both virtual and hybrid. Our technical pipeline is full, with almost 20 technical documents on track to be completed in 2021. There will continue to be significant impact, but there is light at the end of this tunnel. We will continue Connecting People, Science and Regulation® with your help and support. Remember, this is your association. I look forward to hearing from you in the coming year. Happy New Year.

Be safe, be positive and be proud of your contributions. Thank you for all you do!

Best Regards, Mit freundlichen Grüßen, Meilleures salutations, Distinti saluti, Saludos cordials, よろし,

Richard Johnson, President & CEO

Honor Awards

Each year, PDA recognizes members whose contributions have helped PDA

The winners were recognized online and at the PDA Annual Meeting earlier this year. PDA thanks all of the recipients for their contributions to the Association.

Honorary Membership

This is PDA's most prestigious award, conferring lifetime membership benefits to the recipient. The award has usually been given in recognition of very long service, of a very significant nature, to PDA.

Martin VanTrieste

Gordon Personeus Award

Presented in the memory of past PDA President and longtime volunteer, Gordon Personeus, this award honors a PDA member, other than a Board member, for long-term contributions of special importance to PDA.

Morten Munk

Frederick J. Carleton Award

Presented in tribute to lifetime contributor, past President, past Executive Director, and Honorary Member, **Frederick J. Carleton**, this award recognizes past or present Board members.

Joyce E. Bloomfield **Véronique D. Davoust, PharmD**

Martin VanTrieste Pharmaceutical Science Award

Established in honor of long-time contributor and Chair, **Martin VanTrieste**, this award honors outstanding contributions to the advancement of pharmaceutical science.

Edward H. Trappler

Michael S. Korczynski Award

In honor of **Michael S. Korczynski**, PhD, this award recognizes contributions made toward the development of PDA's international activities.

Ivy Louis

Edward Smith Packaging Science Award

In honor of long-time volunteer **Edward Smith**, who led PDA's packaging science activities, this award honors extraordinary contributions to packaging science.

Roman Mathaes, PhD

Distinguished Service Award

Given for special acts, contributions or service that has contributed to the success and strength of PDA.

John D. Ayres, MD **Amanda Jason Kerr** **McFarland, MS**
Dinesh R. Khokhal, PhD **Eiji Watanabe**

James P. Agalloco Award

Named in honor of **James Agalloco's** work in developing the PDA Education program, this award recognizes a PDA faculty member who exemplifies outstanding performance in education.

Marc Glogovsky, MS
Romain Veillon

Distinguished Editor/Author Award

This award is presented for the best editor or author of a PDA-DHI co-published book and is chosen by PDA members.

James L. Vesper, "Root Cause Investigations for CAPA: Clear and Simple"

PDA Letter Article of the Year

Presented to the authors of the most impactful article published in the *PDA Letter* during the year.

Oliver Stauffer, "Industry Must Move Away from Dye Ingress Test"

Frederick D. Simon Award

Presented to the authors of the best paper published in the *PDA Journal of Pharmaceutical Science & Technology*, this award is named in honor of the late Fred Simon, a previous PDA Director for Scientific Affairs.

Marine Marius **Thierry Frédéric Vacher** **Bonnevay**

PDA Europe Service Appreciation Award

Given for special acts, contributions or service that has contributed to the success and strength of PDA's European activities.

Cristiana Campa, PhD

Service Appreciation Award

This award is presented annually for special contributions to PDA.

Masahiro Akimoto	Michael Long
Ursula Busse, PhD	Anette Yan Marcussen
Fabio De Martino	Laurie Masiello
Randy George	Stephan Rönninger
Dinesh Khokhal, PhD	Lisa Rutter
	Karen M. Walker

President's Award

This award recognizes a PDA staff member whose exemplary performance has contributed to PDA's success during the previous year.

Jesse Baker

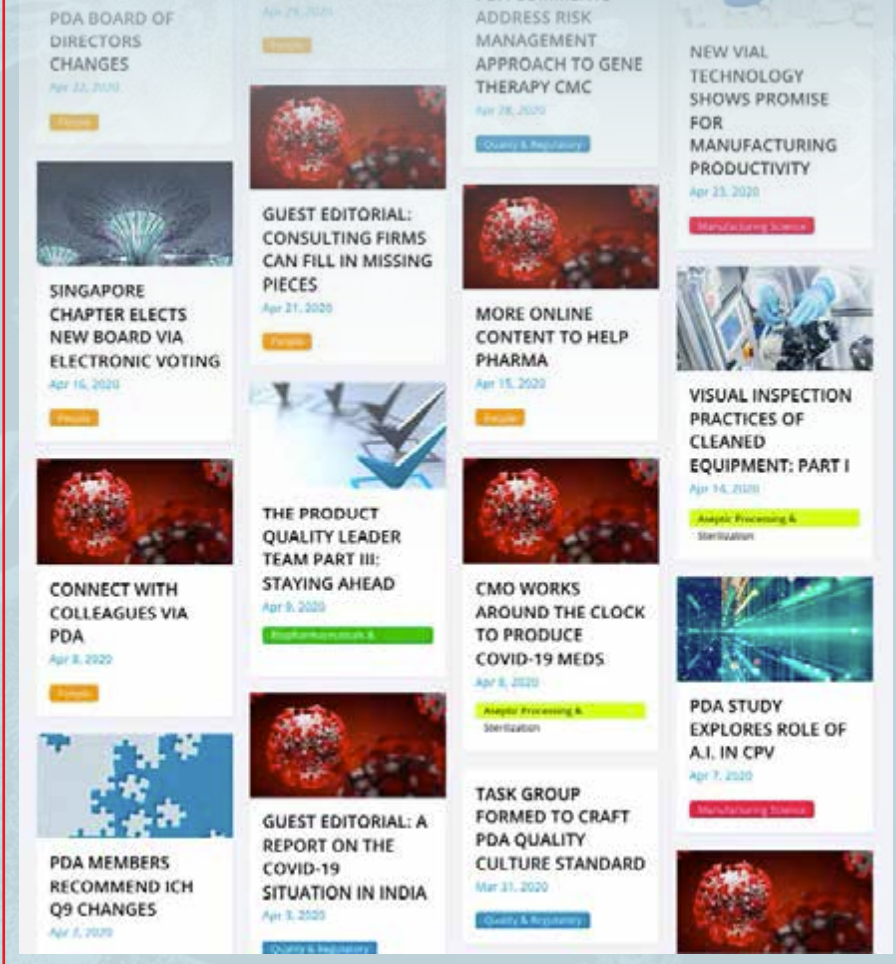
Dirk Stelling

PDA Community Rallies, Adapts During Pandemic

COVID-19 swept across the globe in 2020, disrupting all facets of life, at first in Asia, North America, and Europe before spreading to Africa, South America, and India. Leaders in government, communities, industry, and academia were forced to find new ways of living and operating, relying heavily on web-based technologies to institute the largest wave of remote working seen to date. Shortages of all sorts of products added stress to already psychologically fragile populations around the globe.

All these impacts hit the pharmaceutical/biopharmaceutical industry hard, as those workers who could left their offices for remote work, and those who had to remain on site to produce medically necessary medicines grappled with the new COVID-mitigating procedures, famously including temperature checks, N95 facemasks, and six-foot social distancing. Absenteeism rose, naturally, as people feared the ever-changing reports about the virus. Regulatory bodies ceased almost all on-site inspections for a time, turning to technology to conduct “remote inspections,” just as companies turned to “remote audits” to oversee the manufacturing of their products. Shortages of critical supplies struck industry an additional blow.

Adding to all these pressures, governments around the world called on the industry to heroically develop vaccines to combat the virus. And, remarkably, the industry delivered. Partnering with regulatory bodies to help accelerate clinical development and with material suppliers to ensure a steady supply of ingredients and components, like glass and syringes, several pharmaceutical companies responded and rapidly moved vaccines from the lab to the market by year’s end.



PDA members played a critical role in all of this, forming a COVID-19 Task Force early in the pandemic. Task Force members published, "Controls to Minimize Disruption of the Pharmaceutical Supply Chain During the Covid-19 Pandemic" in the *PDA Journal of Pharmaceutical Science and Technology*, a backgrounder on the virus and its history and an examination of the controls needed to contain it in the context of GMP. The COVID-19 Task Force conducted and published an industry survey on the impact of the pandemic on manufacturers as a precursor to a forthcoming technical report. They produced a series of on-demand podcasts and a webinar series on various topics of importance. And, the Task Force also participated in the regulatory development process, commenting on guidances issued in response to the challenges.

Individual PDA members responded as well, submitting articles to the *PDA Letter* on topics ranging from supply chain disruption to remote inspections and audits throughout the course of 2020.

PDA's response to members' needs was immediate. All in-person conferences and trainings were converted to virtual, online-only events. The Annual Meeting, which was to be held in the very same month closures and work-from-home policies were going into effect, was moved to July and was the first flagship PDA event ever held entirely virtually. A few months later, the PDA/FDA Joint Regulatory Conference followed suit.

Throughout the entirety of the 2020 pandemic, which certainly did not end as 2021 ushered in, PDA and its members continued to produce technical documents, Journal and Letter articles, events, and trainings of the quality the industry has relied upon and expected over the last 75 years. Not once did PDA waiver in its mission to *Connect People, Science and Regulation*®.

PDA Parenteral Drug Association
Connecting People, Science and Regulation®

HOME | EVENTS | TRAINING | TOPIC AREAS | PUBLICATIONS | GLOBAL COMMUNITY | FOUNDATION | JOIN PDA

PDA Coronavirus Task Force

About the Covid 1...
Watch on YouTube

About the Task Force

Task Force Members:

- Adam Caruso, Merck & Co. Inc., Kenilworth, NJ, USA
- Anil Sawant (chair), PhD, Merck & Co. Inc., Kenilworth, NJ, USA
- Callum Chapman, AstraZeneca
- Denise DiGiulio, Johnson & Johnson
- Eva Urban, CSL Behring
- Jim Polarine, Steris Corp.
- Jyothsna Krishnan, GlaxoSmithKline
- Karin Baer, Boehringer Ingelheim
- Madison Hoal, Ecolab
- Martina Kopp, Amgen
- Mary Oates, PhD, Lichman Consultant Services Inc.
- Niraj Mehta, PhD, Merck & Co. Inc., Kenilworth, NJ, USA
- Tiffany Baker, Valsource
- Tom Cosgrove, Partner, Covington & Burling
- Thomas R. Kreil, PhD, Global Pathogen Safety, Takeda

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 circumstances can be managed effectively to the greatest extent possible.

Current Status:

Task force formed and running.

PDA Technical Documents



Regulatory Comments

PDA Comments to WHO Guideline on Data Integrity [15 Jan 2020](#)

PDA Comments to USP on General Chapter <56> [7 Feb 2020](#)

PDA Comments to USP on General Notices Revision [31 Mar 2020](#)

PDA Comments to FDA Guidance on Planning for the Effects of High Absenteeism [29 May 2020](#)

 PDA Comments to FDA Development and Licensure of Vaccines to Prevent COVID-19 [1 Jun 2020](#)

PDA Comments to WHO on Working Document QAS-20.849: Cleaning Validation [30 Jun 2020](#)

PDA Comments to EMA on Annex 1 Revision: Manufacture of Sterile Medicinal Products [13 Jul 2020](#)


PDA Comments to USP on General Notices Revision (Biologics Nomenclature) [31 Jul 2020](#)

PDA Comment to FDA on Guidance on Identification of Manufacturing Establishments in Applications [9 Oct 2020](#)

PDA Comments to FDA on Endotoxin Limits in INDs [29 Oct 2020](#)

PDA Comments to USP on General Chapter <1085.1> Use of Recombinant Reagents in BET [24 Nov 2020](#)

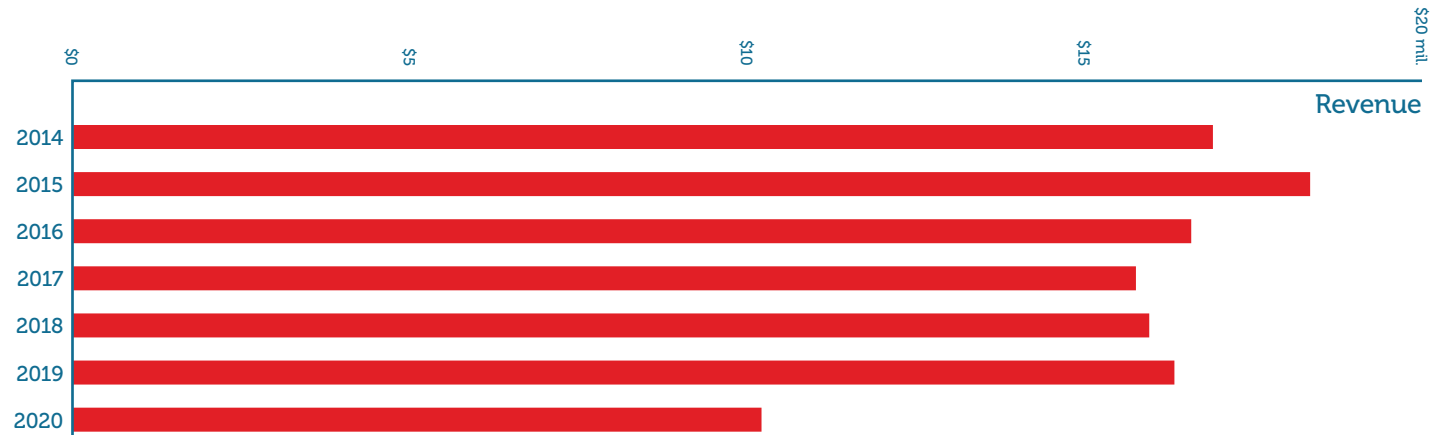
PDA Comments to EDQM on Implementation of Pharmacopoeial Procedures, Chapter 5.28 [31 Dec 2020](#)

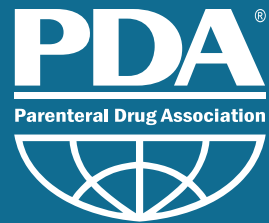
 COVID-19-specific content published

Financials

	2020	2019
Total Revenues	\$ 10,172,434	\$ 17,579,204
Total Expenses ¹	\$ 11,587,919	\$ 18,012,468
Net Income Surplus (Deficit)	\$ (1,415,485)	\$ (433,264)
Increase (Decrease) in Net Assets	\$ (1,415,485)	\$ (433,264)
Net Assets at beginng of year	\$ 8,625,768	\$ 9,059,032
Net Assets at end of year	\$ 7,210,283	\$ 8,625,768
Net Asset ratio (Net Assets/Annual Expenses)	62%	48%

¹ Total expenses includes the foreign currency translation adjustment of \$301,458 in 2020 and (\$21,925) in 2019. This is considered a non-operating expense item.





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