

# PDA Letter

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## Keeping Biopharma's Essential Services Lifeline Afloat During COVID

Subrata Chakraborty, GxPFont Consulting Group

Whoever penned the term “essential services” should have included packaging material manufacturers, laboratory glassware suppliers, HVAC project engineers, and calibration service providers in the list. The lives of patients around the world depend as much on the continuity of operations of these supporting industries as they do on drug manufacturers.

When COVID-19 hit, many of these companies kept operations working with the help of remote access to the machines and other technology. Machine service engineers located overseas guided local service support online to help solve problems.

The most challenging questions that this industry had to quickly answer were:

1. How do you set up an imported machine that needs technical support from the Original Equipment Manufacturer (OEM) with restrictions on international travels?
2. How do you fix your most complex machine problems when they require a manufacturer's intervention?
3. Can you continue the smooth operations of production, R&D, or a QC laboratory with a broken-down supply chain of regular consumables?

The following case studies examine the challenges that the supporting industries unexpectedly faced and how they were overcome.

### SCENARIO 1

**Milieu:** Pharmaceutical manufacturers, especially the ones racing to develop a vaccine for COVID -19, were in dire need of local as well as overseas engineers to complete the final stages of operational commissioning to enable production.

**Challenges faced:** It was to be a leap of faith, because time was the biggest challenge and synchronization of all actions from all quarters was a prerequisite. Having tests for COVID-19 performed, being issued test certificates, gathering tickets and travel gear and observing all the protocols for flying were indeed challenging, but not impossible.

**Actions taken:** Thanks to the network of contacts of these essential services industries, companies mobilized their resources to support their cause and ensure that the engineers were put on the “Vande Bharat Flights” (special flights to repatriate the overseas workmen). Armed with special permissions and express visas to arrive in time for the activities, all clearances and arrangements were made for their smooth transit into and out of the country. Precautions were taken for the assignment at hand, the well-being of teams from every angle was of the highest order.

**Lessons learned:** Travelling is a basic venture taken for granted, and business requirements necessitates it when subject matter experts are required to be on customer sites to erect, commission, repair or pull down the system or equipment. With the rules of quarantine in place, viability of travel and access to solving problems takes longer and costs escalate. The need to establish case- or person-specific quarantine rules instead of a general one-size-fits-all rule emerged.



*Continued on page 11*



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# PDA Chapters

## Your Local PDA Connection

### Are you curious about the issues unique to your region?

Another layer of PDA leadership resides at the grassroots level in the Chapter organizations. Regional PDA Chapters provide local services to the membership, including translations of PDA publications, networking social events, student scholarship and annual regulatory and technical conferences. Each Chapter is managed by volunteer leaders.

**Learn more about your local Chapter at [pda.org/Chapters](http://pda.org/Chapters)**

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# Roller Coaster Year Comes to an End

I can say without any reservation that 2020, has been a roller coaster year for the industry, starting with the interruptions of the PPE supply to creating a safe working environment for employees to redesigning supply and logistics networks in a rapidly changing environment. It has been a dramatic year in which many made leaps into the digital age, much faster than anyone would have considered making during a “normal” year. But as resilience kicked in, pharma has adapted to new ways and processes and retained output and control. Inspections became virtual, and new processes, procedures and technologies were created.

At PDA, we created the COVID-19 Task Force that developed recommendations for the industry. There are some interesting podcast to explore in the website <https://www.pda.org/news/pda-coronavirus-updates>

Our 2020 plan consisted of visiting various countries and participating as thought leaders in various events in the region. Obviously the plan needed to be changed and adapted. Instead, we focussed on moving into digital learning, which became quickly a crowded space. PDA remained active with the members and continues to release new reports and books, and provided much of the e-learning on demand. **[Editor’s Note: See a full list of PDA Education’s Asia Pacific offerings for 2020 on page 9.]**

For 2021 you can expect this to continue. The Asia Pacific Office will work with local advisory committees to create events with content relevant to them, and these committees will recommend what content they’d like to include from the U.S. and EU Meetings. In short, we will bring the meetings to you in a way that suits you. Yes, this will be mainly digital but we remain committed to launch in-person events in the latter half of 2021 should the world slowly return to business travel. We will see what this will bring.

We remain committed to supporting our Chapters in the region, and will continue to offer them way to enable a better and more effective way for their activities and streamline this at the same time with PDA programs.

Finally, I would like to request for your ideas and suggestions on what you think we should be focussing on in 2021 in addition to our current plans. Kindly email me at [ewals@pda.org](mailto:ewals@pda.org).

The Asia-Pacific team wishes everyone a great 2021 ahead. 🍷



Marcel Ewals, PDA Asia Pacific Office



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# 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)

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



**5-6 OCTOBER 2021**

**GOTHENBURG, SWEDEN**

**WORKSHOPS: 4 OCT**

**CONFERENCE & EXHIBITION: 5-6 OCT**

**TRAINING: 7-8 OCT**



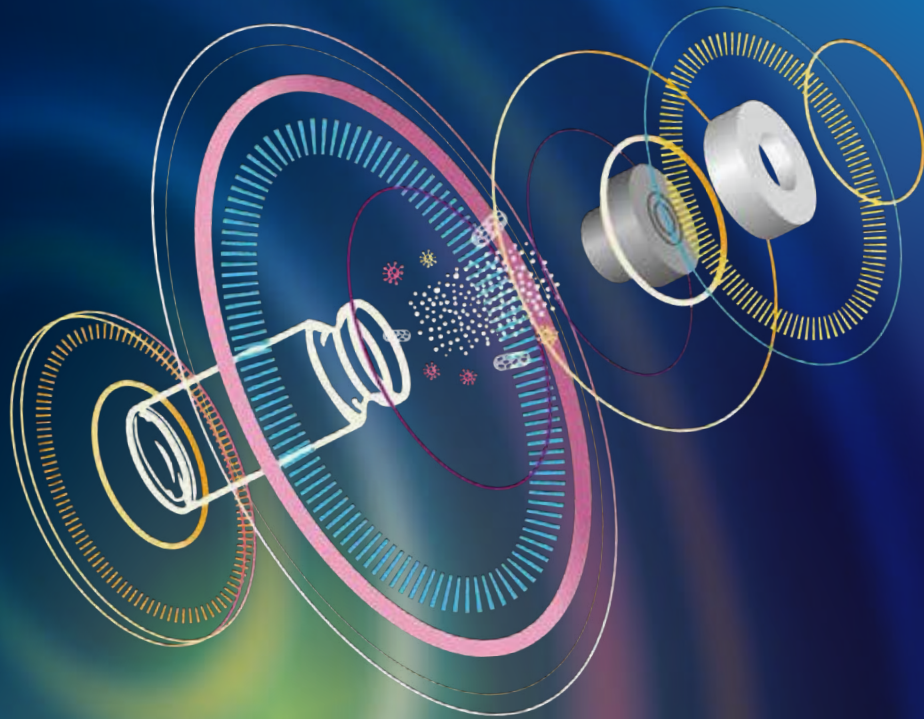
# PDA Education Offered 18 Online Courses to Members in Asia-Pacific and India in 2020

The COVID-19 pandemic hardly slowed down PDA Education. The group used online tools to offer 18 courses to PDA members in the Asia-Pacific region and India. 🍷

PDA 737 Terminal Heat Sterilization	Online – India	Sterilization	04/28/20
PDA 712 Aseptic Processing – Cleanroom Behavior, Health & Hygiene	Online – India	Aseptic Processing	06/15/20
PDA 735 Container Closure Integrity Testing	Online – APAC	Parenteral Packaging	06/23/20
PDA 734 Cleaning and Disinfection	Online – APAC	Cleaning	06/25/20
PDA 598 Regulatory Inspections	Online – India	Quality Assurance	07/07/20
PDA 730 Isolator Technology	Online – India	Aseptic Processing	07/14/20
PDA 247.2 Technical Report No. 70: Fundamentals of Cleaning and Disinfection Programs for Aseptic Manufacturing Facilities	Online – APAC	Cleaning	07/15/20
PDA 619 Visual Inspection – India	Online – India	Visual Inspection	08/11/20
PDA 732 Filtration	Online – India	Filtration	08/18/20
PDA 374.1 Technical Report No. 22: Process Simulation for Aseptically Filled Products	Online – India	Aseptic Processing	08/24/20
PDA 735 Container Closure Integrity Testing	Online – India	Parenteral Packaging	09/29/20
PDA 853.1 Environmental Monitoring	Online – India	Environmental Monitoring	10/06/20
PDA 724 Aseptic Processing - Gowning, Qualification, Requalification	Online – India	Aseptic Processing	10/19/20
PDA 374.1 Technical Report No. 22: Process Simulation for Aseptically Filled Products	Online – APAC	Aseptic Processing	11/17/20
PDA 712 Aseptic Processing - Cleanroom Behavior, Health & Hygiene	Online – India	Aseptic Processing	11/30/20
PDA 853.1 Environmental Monitoring	Online – APAC	Environmental Monitoring	12/01/20
PDA 247.2 Technical Report No. 70: Fundamentals of Cleaning and Disinfection Programs for Aseptic Manufacturing Facilities	Online – India	Cleaning	12/08/20
PDA 726 Aseptic Processing - Facilities	Online – India	Aseptic Processing	12/15/20

# 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**

Keeping Biopharma's Essential Services Lifeline Afloat During COVID continued from page 1

The basic lesson learned is that, with due logic and applying common sense in the situation, workable solutions can be identified, planned and implemented. This pandemic is not going to end soon, and industry will have to fine tune its modus operandi to circumvent the hurdles accordingly.

## SCENARIO 2

**Milieu:** The challenges faced by the regular manufacturing and laboratory consumable suppliers due to continued lockdowns in the country are related to on-time delivery of their products and services to the customers in pharmaceutical and biotech industry. Even after relaxation of the lockdown norms now, they continued to face challenges to serve customers due to sudden lockdowns or restrictions that are imposed by the local municipal authorities.

**Paramjyoti Chakraborty**, country head of BRAND Scientific Equipment, a leading laboratory instruments and consumables supplier in India, says:

“We are very much affected due to the lockdown norms. This has resulted in a cost escalation of around 25% in logistics apart from the increased cost of imports due to unavailability of passenger airlines helping in small cargo movements. So, for our products that qualify as premium products, especially for the pharmaceutical R&D and QC laboratories, we are left to bear this additional cost as a burden. Further, with limited cargo options on the international

circuit, we are also forced to build up our inventories, since our customers working on various life-saving products can't keep waiting for our products.”

**Challenges faced:** On-time delivery of the products and services at customer sites was most crucial. Due to various uncertainties, such vendors did not have enough time to plan their orders: either they received a sudden spike in demand, or they had inventories that remained on their shelves for weeks because of no demand.

“The transportation of instruments to the customer sites were nerve-wracking experiences due to the disruptions in supply chain and logistics services,” says Chakraborty.

**Actions taken:** The key actions involved increasing inventory-carrying norms, focusing on effectiveness of supply chain and introducing innovative approaches towards after-market services like product training and product service support, mostly through virtual means with limited physical presence by local resources.

Chakraborty explained, “To stay connected with our customers for our support, we are available on almost all online platforms based on customers' choice. We have created product application videos for our customers that we use during the online meetings to demonstrate our products and we also provide virtual runs for some of our high-end products with inputs from our customers to their application requirements.

“On the internal side, we have updated our systems and continuously train all our team members with knowledge updates to deal with this changed scenario so that they can efficiently and seamlessly work with their customers, service providers and vendors.”

**Lessons learned:** The learning comes every hour and every day. Business agility with people, and the ability to shift gears with processes, is what will help sustain this industry in the post-COVID era.

## Where do we go from here?

The next few quarters could remain as challenging as it has been for all ancillary businesses related to the biopharmaceutical and pharmaceutical industries, with shortages of the workforce, the uncertainty of demand, and the increasing cost of operations.

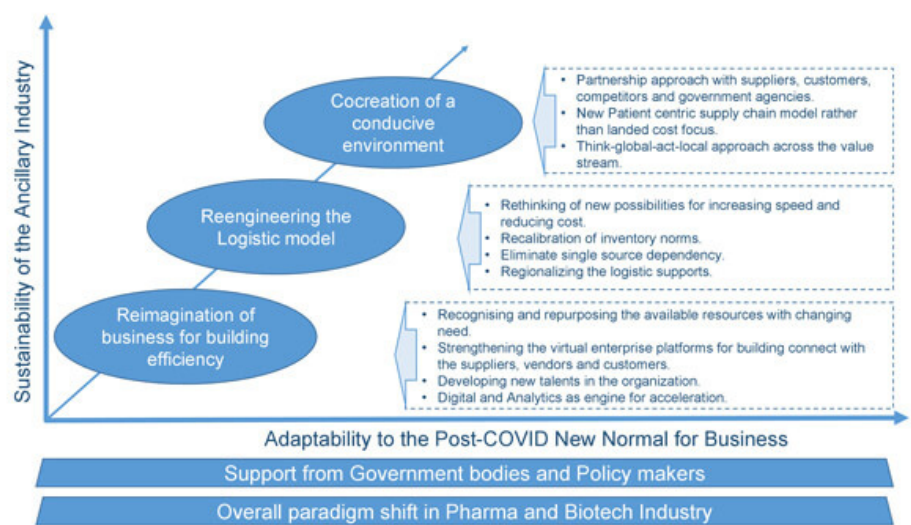
To maneuver through these choppy waters, first the business leaders of these industries must build better visibility of their entire system. This will come from adopting advanced technologies and digitizing their operations and supply chain networks. Next, efficiency in operations must be strengthened to meet the changing needs of the business and yet remain competitive. This would also call for building more of a regionalized structure than a global structure, investing in local talents, and ensuring the overall adaptability to these new business norms. The success of this entire ecosystem will depend upon the ability to co-create a business environment that will move towards a new patient-centric business model. **Figure 1** depicts the path forward for ancillary industries.

## Conclusion

Indeed, these are turbulent times, but the bright side is the innate adaptability and resilience that businesses in the essential services have displayed to make things work.

## About the Author

**Subrata Chakraborty** volunteers for the PDA Letter Editorial Committee for Asia Pacific region. He leads the GxPFONT Consulting Group as Principal Advisor and has over 24 years of experience in handling pharmaceutical manufacturing and quality operations in various capacities with subject matter expertise in Aseptic Technology. 🍷



**Figure 1** Path Forward for Ancillary Industries



# Chemical Durability Ratio: Method Provides Leading Indicator of Delamination Risk

Robert Schaut, Kelly Murphy (formerly), Daniel Kramer, Christy Chapman, and Carol Rea Flynn, Corning Inc.



Glass delamination has been at the forefront of the pharmaceutical industry since the FDA published its advisory in 2011.

The term delamination refers to the production of thin, visible, glassy particles in a drug product following a corrosion process. Formation of delamination particles has been linked to heterogeneous (non-uniform) surface chemistry in the heel area of the glass vial generated during the tube-to-container converting process. An improved approach to assessing delamination risk based on the degree of non-uniform surface chemistry is recommended. Benefits of this method will be compared to existing screening strategies that rely upon lagging indicators and lamellae generation.

While chemical characterization techniques (DSIMS, XPS and SEM) are well-suited to evaluate changes in surface chemistry that have been linked to delamination, they have limitations, including: high cost, significant analysis time/technical training, influence of sample preparation and small area investigated (less than 1 mm<sup>2</sup> on one part). Current delamination testing methods, such as *USP <1660> Evaluation of the Inner Surface Durability of Glass Containers*, are also not sufficient for a definitive determination of delamination risk. These methods rely upon observation of glass lamellae, which frequently do not occur within the recommended testing timescales but could appear later or be dissolved due to aggressive test conditions. Also, some methods (such as those

described in *USP <1660>*) lack prescriptive detail, leading to differences in test methods (from lab to lab) and qualitative, noncomparable results. This new method, chemical durability ratio (CDR), characterizes the degradation of chemical durability due to surface heterogeneities present in some pharmaceutical glass containers. It is intended to complement the compendial *USP <660> Surface Glass Test* and applies to containers that already meet Type I performance criteria.

As pictured in **Figure 1**, the method consists of:

1. A hydrolytic test of the “as-received” surface
2. An etching step to remove any chemical heterogeneities that may be present

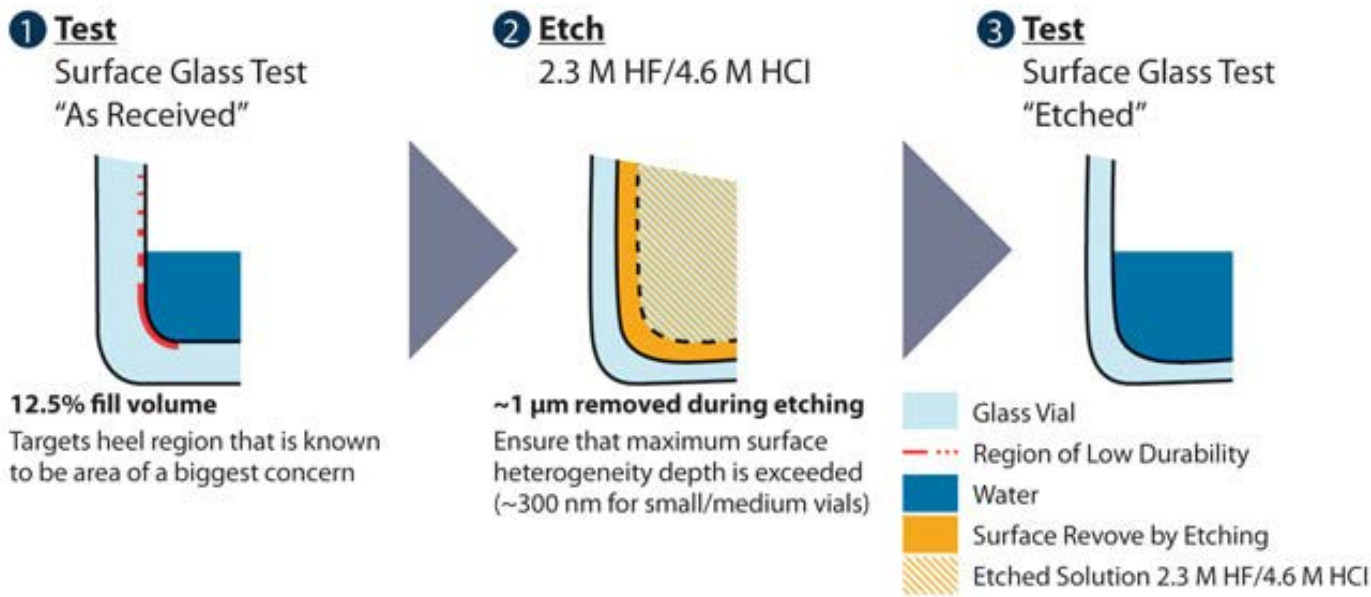


Figure 1 Schematic of the major steps in the CDR test method

$$\text{Chemical Durability Ratio (CDR)} = \frac{\text{① "As-received" vial titrant volume}}{\text{③ Etched vial titrant volume}} \approx \frac{\text{<660> Surface Glass Test*}}{\text{<660> Surface Etching Test*}}$$

\*At reduced volume

Figure 2 CDR mathematical expression

3. A second hydrolytic test of the "etched" surface

"As-received" containers are processed according to USP <660>, with one notable deviation: the filling volume is 12.5% of the brimful capacity. The low filling volume is used to focus on the glass surface area that would be in contact with drug solution and that exhibits degraded durability, e.g., heel area. The titration volume is recorded as the "as-received" response.

A second surface glass test is conducted on "etched" containers to measure the bulk glass response, again at the reduced 12.5% filling volume. The etching process removes the material deposited or incorporated during the converting or molding process. At least one micron (depth) of the

surface is removed using a mixture of hydrofluoric and hydrochloride acids, with target concentrations of 2.3 M HF/4.6 M HCl. The containers are exposed to this solution for a minimum of three minutes. These conditions are sufficient for most glass compositions, and the mass lost is measured to confirm sufficient depth of surface removal. After exposure to the target acid solution, acidic residue in the containers is removed through soaking in two room temperature water baths for five minutes each. Subsequently, the containers are rinsed with high-purity water several times. Containers used for the "etched" response can either be a completely unique set or the retained containers from the "as-received" test. The "etched" containers are processed according to USP <660>, using the reduced fill

volume (12.5% of the brimful capacity). The resulting titrant volume is recorded as the "etched" titrant response.

A ratio of the recorded titrant volumes, as illustrated in **Figure 2**, provides a measure of the level of surface heterogeneity.

Containers with uniform surface chemistry have the lowest risk of delaminating, and they exhibit CDR ratios between ~0.5 and ~2.0. Containers converted with care to produce minor heterogeneities will have CDR ratios between ~2.0 and ~5.0. While lower values are preferred, containers with higher CDR values in this range (e.g., 4.0) will have an increased risk of delamination and should only be paired with solutions of low corrosivity. Containers with CDR values greater than 5.0 are known to con-



tain heterogeneities sufficient for delamination. The exact time required for the corroded regions to spall off into solution as a delaminated flake will depend upon the corrosivity of the solution.

The CDR results show vials deemed “Type I” by USP <660> and *Ph. Eur. Glass containers for pharmaceutical use (3.2.1)* can include a large range of chemical durability. The CDR method has been shown to quantitatively distinguish populations with known performance variation (i.e., delaminating populations). Surface characterization results confirm that vials with measured CDR values closer to 1.0 have more consistent surface chemistry (relative to the underlying surface) and are at lowest general risk for delamination. Glass manufacturers might utilize this method to understand and improve their products or implement process control. Similarly, pharmaceutical companies might employ the method during container selection (to understand relative risk and performance between container options) and during manufacturing (to monitor incoming container quality).

This new CDR method offers significant advantages for evaluating the risk of delamination compared to existing screening strategies. This screening targets the typical drug-glass contact surface with pharmaceutically relevant fill volumes, samples a larger population of containers and requires less time relative to other test methods. In addition, this method can quantify differences in chemical durability when heterogeneities are present and can be easily implemented in a pharmaceutical or glass supplier laboratory.

For more information on this method, [click here \(pdf file\)](#).

### About the Authors

**Robert Schaut**, PhD, is a Scientific Director for Corning Pharmaceutical Technologies at Corning Incorporated. He



currently communicates the science of glass parenteral packaging to customers and guides regulatory strategy and research in support of CPT at Corning’s Global Research site, Sullivan Park. Schaut specializes in the study of chemical and physical properties of glass surfaces and has co-authored 13 peer-reviewed articles, 100 technical reports, and more than 70 patent applications, including that for Valor® Glass.

In her former role at Corning Incorporated, **Kelly Murphy**, PhD, was a Development Scientist with a focus on understanding chemical interactions of glass surfaces. Kelly developed novel methods for product release testing and authored DMFs for pharmaceutical containers.



**Dan Kramer** is a Senior Development Scientist at Corning Incorporated in the Product Development group. He serves as an expert in surface chemistry and the corrosion of glass materials.




**Christy Chapman** serves as Senior Product Development Engineer for Corning Pharmaceutical Technologies at Corning Incorporated. Her 21-



year career includes time in the polymer research department, with a majority of her career in the fundamental glass research group including work on glass composition and melting, tubing characterization, chemical reliability, glass surface understanding and thermal properties.

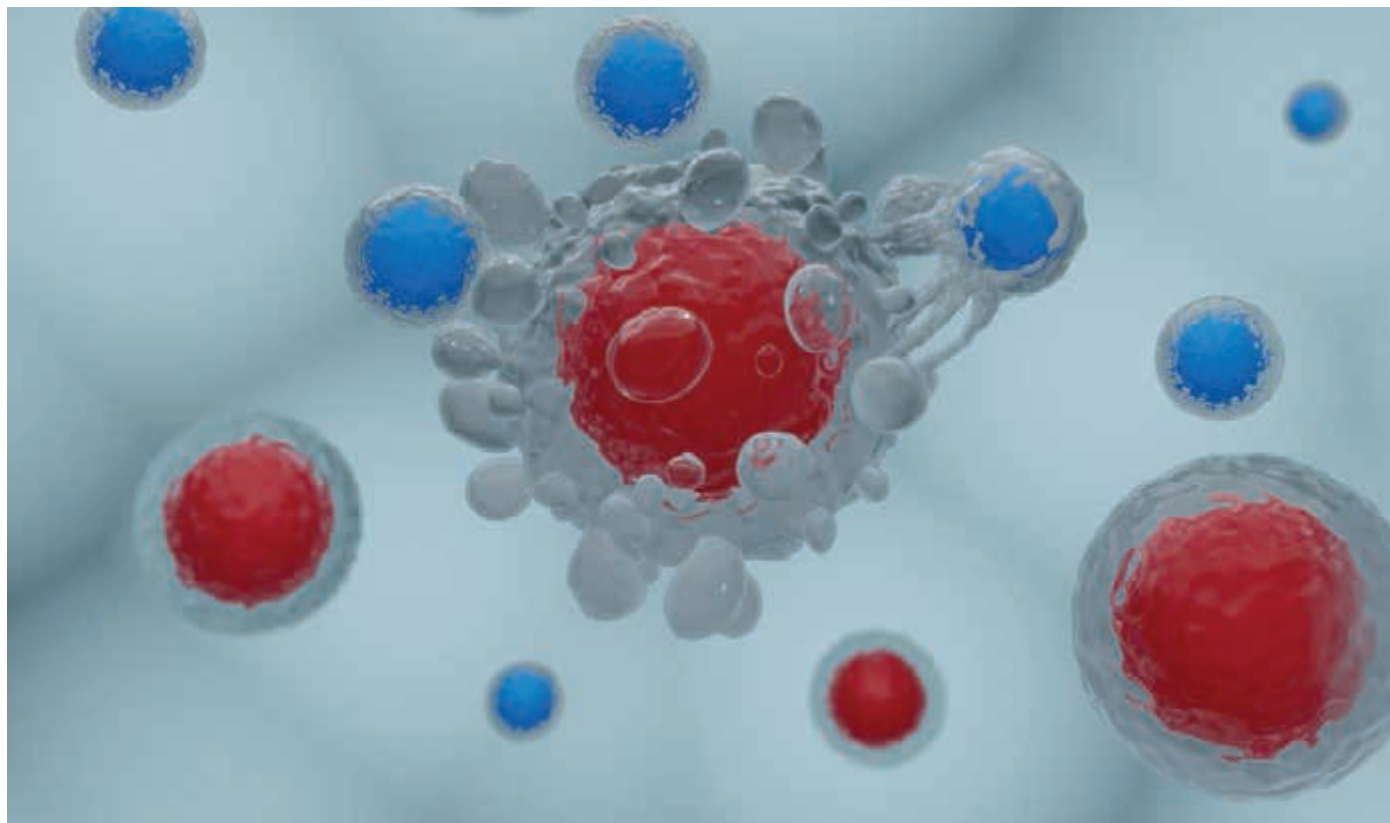
**Carol Rea Flynn** is currently the Glass Standards and Technical Services Manager for Corning Pharmaceutical Technologies at



Corning Incorporated. Her 30 years’ experience in the pharmaceutical glass industry includes involvement with Engineering, Manufacturing, Quality, Regulatory Compliance and Technical Services. She is an active participant with pharmaceutical glass packaging advocacy groups (ICG TC12, PDA, ASTM, USP). 

# T-Cell Therapy Saves a Life

Marilyn L. Foster, PDA



Emily Whitehead was diagnosed with standard-risk pre-b acute lymphoblastic leukemia when she was only five years old. After two rounds of chemotherapy, an infection that almost cost her both legs and a full relapse, she became Patient 1 in a Phase 1 trial of T-cell therapy.

In the opening sessions of the *2020 Virtual PDA Annual Meeting* (Jul. 20 – 22), **Tom G. Whitehead** shared the moving story about how T-cell therapy saved his daughter's life, and **Elliot C. Norry**, MD, Chief Medical Officer of Adaptimmune, described how these life-saving therapies work.

In his presentation, “Delivering T-Cells to Patients: Challenges and Successes,” Norry explained the Autologous Specific Peptide Enhanced Affinity Receptor (SPEAR) T-cell therapies his company develops for the treatment of cancer. T-cells, a group of white blood cells that help find and fight things foreign to the body like bacteria

and viruses, attack and clear them using an inflammatory response. Adaptimmune has developed SPEAR T-cells that specifically recognize certain cancer cells as foreign and target them.

“Behind every bag of SPEAR T-cells manufactured,” Norry stressed, “is an individual living with cancer.” And the individual is usually a patient with an advanced form that has not responded to other treatments.

He illustrated the patient's journey from leukapheresis to infusion and the process of engineering the SPEAR T-cells. Adaptimmune ships the modified T-cells back to a patient's treatment center; the whole process usually takes 22-25 days. Before being infused with their SPEAR T-cells, the patient undergoes lymphodepleting chemotherapy to “make space” for the incoming cells and improve the efficacy of the treatment.

Several factors present a challenge to the process, Norry noted, starting with the fact that each product batch is unique to the patient.

The apheresis starting material and the cell dose range will vary depending on the patient's age, health and prior treatments, meaning no two products ever look the same. As such, a strict chain of custody must be maintained, location and temperature of the cells monitored at all times, and special measures taken to ensure that patients receive only their own cells.

Aligning patient scheduling with manufacturing capability creates a need for flexible capacity, requiring Adaptimmune to maintain control of the entire process. The growing success of the treatment in several different advanced cancers is why the company continues to pursue SPEAR T-cell studies, to improve the process and increase the availability of the treatment across a broader population.

### Putting T-Cells to the Test

Whitehead enthusiastically supported T-cell therapies in his presentation, “Journey to Car-T Cell Therapy,” where he detailed the steps his family took to save their daughter Emily.

Following Emily’s diagnoses, Whitehead consulted with oncologists from Pennsylvania’s Hershey Medical Center and Children’s Hospital of Philadelphia (CHOP). They started Emily on outpatient chemotherapy at Hershey as it was “only a two-hour drive instead of four.” Soon after, she awoke one night with severe pain in her legs; she had developed infection in both legs, necrotizing fasciitis. The ER doctor said they may have to amputate both legs to save her. Whitehead remarked, “We had started with hope. Now we were really scared.” Fortunately, the infection was not in the muscle, but around it, so amputation wasn’t necessary, and Emily went back to chemo.

The majority of children with ALL are cured after a two-year treatment with standard chemotherapy and, initially, that worked. But 16 months later, Emily “felt the cancer in [her] bones again.” Despite the two rounds of chemo, a bone marrow test confirmed it. Because Emily went into full relapse, she was no longer considered a “standard risk” and a bone marrow transplant was not an option. All Hershey could offer was another round of more intense chemo.

Whitehead got a second opinion from **Susan Rheingold**, MD, at the CHOP Cancer Center, but received the same answer, so they continued treatment at Hershey, seeking a donor for an allogeneic stem cell transplant. One was found and the transplant was scheduled for February 2012, but before then, Emily relapsed again.

Her leukemia was so aggressive this time, doctors recommended Whitehead take Emily home for hospice care. Not giving up, Whitehead applied for an experimental clinical study of CAR T-cell therapy at

CHOP. The study was underway, but the therapy had never been used on children. In the meantime, Emily underwent a new chemo they knew “wouldn’t cure her but would give her some time.”

It proved to be just enough, as soon the T-cell therapy clinical trial was approved, and in April 2012, Emily became Patient 1 in the Phase 1 pediatric trial.

As the doctor explained the process to Emily, they would use her T-cells to “build an army that would fight the cancer,” and took her T-cells “off to boot camp.” With no immune system, Emily remained in isolation for six weeks. When it was time to return her strengthened army of cells, they infused her in a stepped process—10% one day, 30% the next, 60% the last—to determine what was effective and to evaluate her reaction, especially since they had no existing protocol for dosing a child. Emily withstood the first two doses well, not even showing the flu-like symptoms the family had expected, but the final dose knocked her out.

After receiving the 60% dose, Emily experienced cytokine release syndrome, a “cytokine storm” that brought on a raging fever (106 °F at one point), chills, hallucinations, labored breathing and a sudden drop in blood pressure. She was put on a ventilator and induced into a coma to relieve the pain; the steroids they pumped into her to reduce pain and inflammation, instead swelled her body beyond recognition.

The doctors gave Emily a one in one-thousand chance of surviving the night, but Whitehead asked her to try to get through it, held her hand throughout the ordeal and told the doctors, “just don’t give up on her.” Emily kept fighting throughout her 14-day coma.

Whitehead said, one test revealed her interleukin-6 level was “higher than anyone alive,” 1000 times above normal. By chance, **Carl H. June**, MD, who led the clinical team at the University of Pennsyl-

vania, recognized the IL-6 protein as one involved in rheumatoid arthritis, a disease that afflicted his daughter. He determined that Emily be treated with tocilizumab, the drug his daughter takes, though it had never been used in cancer patients. The results were dramatic! Within hours, her fever was down, her breathing came easier and her blood pressure normalized. She woke a week later on her seventh birthday. Twenty-three days after that, she texted her family “no cancer cells, T cells worked!” Eight years later, Emily is still cancer-free, thanks to the T-cell therapy that turned her life around.

In the Q&A that followed his presentation, Whitehead replied that Emily is now a typical 15-year-old girl who, while hanging out with her family in isolation during the pandemic, spends lots of time texting friends. As a strong supporter of T-cell therapy, Whitehead and his wife, Kari, started the Emily Whitehead Foundation to help other families navigate childhood cancer and advocate for pediatric cancer research so others can have the same positive outcome as Emily.

Asked about the future of cell therapies, Norry said, “Harnessing a patient’s *own* immune system to help fight cancer makes sense. I don’t know what the future looks like, but I hope it expands to help more patients even earlier in their course of therapy.”

### About the Author

**Marilyn Foster** is PDA’s Technical Editor/Writer who works with volunteers to prepare PDA technical reports and other documents. She has more than 20 years of experience writing/editing for the pharmaceutical industry, for the Nonprescription Drug Manufacturers Assn. and the U.S. Pharmacopeia. During Covid, she has moonlighted writing articles for the PDA Letter. 🍷



# PDA President Richard Johnson on the Impact of COVID-19 on the Supply Chain

**Note:** From Richard Johnson's Presentation on COVID-19 to the PDI Congress 2020 in September. Richard repeated this presentation at the Australia Chapter End of Year Virtual Event on 8 Dec 2020. 🇺🇸

**SUPPLY CHAIN ISSUES**  
**供应链问题**

- Disruption of Supply Chain 供应链中断
- Demand Increases 需求增加
- Need for Resilience 弹性需求
- Regulatory Response 监管回应

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**Supply Chain Disruption 供应链中断**

- With the virus still a live threat and a number of regions and economies in lockdown, while others emerge into a very different world, the disruption to supply chains continues to beset us.

由于病毒仍然是一个活生生的威胁，许多地区和经济体仍处于封锁状态，而其他一些地区和经济体则进入了一个截然不同的状态，供应链受到的破坏仍十分严重。

**94%**  
of Fortune 500 companies are working under their programs from COVID-19.

- Business leaders must make rapid decisions and take immediate actions to sustain business operations to serve their customers, clients and communities, as well as protect and support their workers.

企业领导人必须迅速做出决定，立即采取行动，维持企业运营，为客户和社区服务，并保护和支​​持员工。

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**Supply Chain Demand increases**  
**供应链需求增加**

- Initial impact was on PPE – dramatic increase in demand, impact on healthcare workers

最初的影响是个人防护装备——需求量急剧增加，对医护人员产生影响

- 2<sup>nd</sup> impact – rapid development of diagnostics

第二个影响——诊断法快速发展

- 3<sup>rd</sup> impact – dramatic increase in demand for ancillary drugs needed for respiratory failure (anesthetics, antibiotics,

第三个影响——呼吸衰竭所需辅助药物（麻醉药、抗生素）的需求急剧增加

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**Supply Chain Need for redundancy**  
**供应链冗余需求**

- The repurposed and reshaped supply chains of the future will need to be characterized by both resilience and responsibility.

未来重新利用和重塑的供应链需要兼具弹性和责任担当力。

- These will help communities manage the short-term crisis and enable businesses to build around their customers and help economies rebound.

这将帮助社区管理短期危机，使企业能够围绕客户开展业务，并帮助经济反弹。

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**Drug Shortages 药物短缺**

- Many pharmaceutical drug products have the potential to be in short supply due to increased demand to treat hospitalized COVID-19 patients.

由于住院治疗COVID-19患者的需求增加，许多药品有可能出现供应短缺。

- Shifting production schedules to meet this increasing demand will help but may create backorders for other needed drugs.

调整生产计划以满足日益增长的需求将有所帮助，但可能会导致其他所需药品的订单积压。

- The disruption to the supply chain due to absenteeism of production and testing personnel, warehousing and shipping of packaging components, pharmaceutical ingredients and finished products and imposition of national trade barriers to the free distribution of pharmaceuticals are all serious concerns.

由于生产和检测人员的缺勤、包装组件、药品成分和制成品的仓储和运输以及对药品自由分发施加国家贸易壁垒而造成的供应链中断都令人十分担忧。

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**Drug Shortages (cont.) 药物短缺 (续)**

- Shortages have been reported for drugs that are used to keep patients' airways open, as well as antibiotics, antivirals and sedatives.

据报告，用于保持患者气道畅通的药物以及抗生素、抗病毒药物和镇静剂供应出现短缺。

- Orders for broad-spectrum antibiotics like azithromycin and antiviral like ribavirin have tripled; medicines for sedation and pain management like fentanyl, midazolam and propofol have increased by 100, 70 and 60% respectively.

阿奇霉素等广谱抗生素和利巴韦林等抗病毒药物的订单增加了两倍；用于镇静和止痛的药物，例如芬太尼、咪达唑仑和异丙酚，需求分别增加了100%、70%和60%。

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**Regulatory Response to the COVID-19 Outbreak**  
**对COVID-19爆发的监管行动**

- All major health authorities began monitoring and developing action plans early in 2020.

所有重要卫生部门在2020年初开始监测和制定行动计划。

Actions included:

这些行动包括:

- Suspension of travel for inspectors

暂停检查员出游

- Accelerated review of diagnostics and therapies

加速诊断和治疗检查

- Monitoring shortages

监控短缺

- Emergency Use Authorizations to permit importation and allow usage of products with limited data, under clinical observation

紧急使用授权以在临床观察的情况下允许进口和使用数据有限的产品

- Publication of guidance for various pandemic related issues

就各种与疫情有关的问题发表指导意见

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