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Lessons Learned During The Coronavirus – Covid-19 (SARS-CoV-2) Pandemic



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IVT Network is committed to keeping you informed on COVID-19 and industry impacts and changes

These past several weeks have become a test in global resiliency, solidarity, creativity and good old fashioned grit. As the COVID-19 pandemic spread across the globe challenging community leaders to close, businesses, schools, shopping centers, restaurants and parks, citizens self-isolated in an effort to "flatten the curve." Under stay at home orders many countries extended mandates that won't expire until May or even June. Meanwhile, hospitals continue to receive a constant flow of new patients, medical and household supplies remain scarce and citizens stuck at home grow weary of the isolation and the "cabin fever" is beginning to show. Despite the obvious challenges for everyone, we have learned several critical lessons these past few months. New content on the IVT Network particularly relevant to journal readers has contributed to these lessons learned.

Remote Work Really Works

All non-essential employees have shifted to work-from-home scenarios, a task never thought possible in some industries. Yet in a relatively short amount of time the shift to remote work has been accomplished, and most industries continue to productive in some capacity. Those that aren't working remotely abide by social distancing guidelines capping the number of people admitted based on square footage, maintaining the 6-foot recommended safe zone and boosting sanitization and disinfecting efforts. From research laboratories to clinical testing sites we hear of collaborative efforts from afar using online tools such at Google Drive, Slack, WhatsApp and Zoom, to name a few.

For many in the life sciences, this may be a temporary fix, but looking further down the road this may be a new way of living and working. We will wait to see if this "trial run" at remote work spurs a bevy of new work-from-home positions, eliminating a need for commercial real estate and expensive office equipment

A BIG shout out to all of the frontline workers who have made sacrifices for those infected by COVID-19 and other. To hear more about the first cases of SARS-CoV-2 you can check out this video created by IVT Advisory Board member, Bernard Hsu. Several videos by Dr. Hsu are posted, including content on several newsworthy topics. These videos also contain additional links to related Covid-19 content.

Digital Access is Critical

The global shift to remote work is only one small indicator of the need for connectivity in our quest to maximize productivity. As the pandemic wears on we have seen tele-medicine emerge, a remarkable service for patients all over the world to receive professional care no matter where the live. Digital access is now a necessity indicating that better internet service (broadband) should be considered a basic service. Also dependent on strong access to digital are the virtual labs that have popped up (or continue to run) providing essential testing and research in the race against the clock to find anti-viral, vaccines and alternative therapies for the COVID-19 virus and its subsequent symptoms. Students across the US, and beyond, are able to continue with educational objectives because of e-learning capabilities. Without ready access to internet service a shift of this magnitude would have taken much longer to accomplish. Investing in proper broadband capabilities and global Wi-Fi options may become a much higher priority for some countries as a result of COVID-19. See our blog post on COVID-19 Personnel and Safety Issues for the latest information.

Missing Links in the Supply Chain

Almost from the onset of this global pandemic the world began experiencing shortages of key products necessary to the safety and well being of our front line workers, their patients and the general public. Items like N95 masks, ventilators, gloves, test kits, and hand sanitizer. Across the US shortages of household essentials like toilet paper, paper towels and napkins, cleaning supplies and disinfecting products and of course most shelf stable foods like beans, rice and pastas were at a premium. While some of these shortages may have been short lived, the recovery time for others will be much longer.

Understanding just where the gaps are in the supply chains and how to circumvent a repeat of this in the future is the key lesson here. Discussions for the future include more localized supplier selection, stricter supply chain management, the role of digitization in supply chain, preparing or the disasters before they occur, and of course the ability of regulators to alter or waive certain regulatory guidelines for temporary purpose. How have all of these things impacted our current situation in the midst of a pandemic, and what do each of these things mean to the future of supply chain?

You can find two great episodes on supply chain in the Voices in Validation podcast.

- Supply Chain Management During Times of Uncertainty
- COVID-19 and the Increased Demand for Personal Protective Equipment

Cybersecurity More Important Than Ever

From Zoom-bombing to fraudulent sales of counterfeit PPE products, the pandemic has also shown us just how important having appropriate security measures in place is to the flow of business.

Cloud based applications are used in many industries in a variety of ways. Inherent security risks are present in most internet reliant systems, but industries for whom GxP compliance is necessary require higher standards and added data integrity checkpoints. Guidelines for data integrity and quality control are in place to assist in avoiding these types of breaches. You can listen to the discussion on this topic in the Voices in Validation episode Managing Data Integrity in the GCP Environment.

Creativity Can Overcome Adversity

Creative partnerships. Creative Solutions. Creative Delivery. All the best highlights from the COVID-19 experience have come from outside the box thinking, agile response and innovative solutions. When faced with unfavorable situations, from paramount proportions of crowded hospitals and clinics, to the minor annoyance of chapped hands from washing so much, it's the creative responses that keep us moving forward.

A shout out for setting a great example of partnership. The collaboration between CSL Behring, BioTest, BPL, LFB, Octapharma and Takeda. All leaders in the plasma-focused biopharmaceutical space, they have banded together on a treatment made from the plasma of patients who have recovered from COVID-19.

Kudos to the countless trades professionals who collected much needed N95 masks meeting the FDA equipment requirements and donated them to frontline workers desperately in need. Other creative solutions came from distillers and perfumeries with their quick production of hand sanitizer mixtures. While manufacturers like Dow, Nike, Under Armor and a host of others converted production to PPE safety equipment.

A pat on the back for all of the quick thinkers innovating ways to deliver the best in healthcare – telemedicine to the creation of WHO's EpiBrain warning System; – as well as the best in home delivery, while the world practices social distancing from

home. We saw companies innovate to deliver everything from meals and beer, to groceries, clothing, pet supplies and home décor, all at low or no cost.

IVT Covid-19 Content

Additional content relevant to the pandemic are posted in the journals and network. This issue of the April JVT contains "
The Survival of Coronavirus Sars-Cov-2 On Surfaces and Designing Disinfection Strategies To Eliminate The Virus," and "
Consideration Of Covid-19 Prevention Measures For Those Working In GMP Pharmaceuticals And Healthcare Facilities," both by Tim Sandle. This issue also contains "What, How, and Why of Handwashing" by Paul Pluta. Relevant guidances published by FDA and by USP are also available on the website.

Thank you to our experts, authors and guests, who contributed to this compilation of great information including: **Tim Sandle**, **Siegfried Schmitt**, **Chris Wubbolt**, **Bernard Hsu**, **Igor Gorsky**, **Alan Schwartz**, **Jeffrey Baird**, **Alan Mancini**, and **Paul Pluta**.

For all of the latest news stories and updates you can visit our blog hub or listen to our Voices in Validation weekly podcast.

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