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# Brief spots on autumn conferences

## PDA and ISPE offered virtual conferences with interesting insights in September 2020

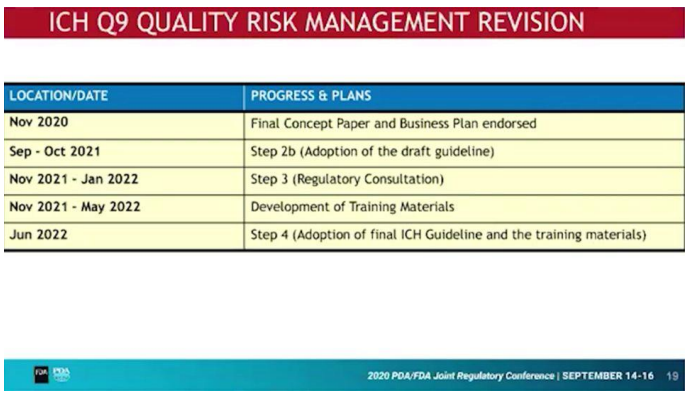
by Thomas Peither

In September 2020 the series of virtual autumn conferences of PDA and ISPE started. We were present and pick out some excellent sessions with this LOGFILE feature.

### The most critical ICH revision: ICH Q9

The conference season started in September with the virtual *PDA/FDA Joint Regulatory Conference*. Sabine Paris followed among others the intriguing lecture of of Roger Nosal, Pfizer and Rapporteur of the ICH Quality Discussion Group.

He presented a schedule for the ICH Q9 Quality Risk Management Revision, with the final revision expected in June 2022. Details are shown in the figure.




Nosal described the revision as the "most critical revision", as quality risk management now plays a leading role in many topics.

The objectives of the revision are adjustments to specific chapters and annexes of the current guideline and the development of specific training materials for the proposed revisions.

The adjustments shall cover e.g.:

- High levels of subjectivity in risk assessment and in QRM outputs
- Product availability risks
- Lack of understanding as to what constitutes formality in QRM work
- Lack of clarity on risk-based decision-making

### "The prepared mind will be the catalyst of change."

A few days later the virtual *ISPE Europe Annual Conference* demonstrated a strong and robust understanding of GMP in Europe.

Udo Vetter, Chairman of the Advisory Board, Vetter Pharma, presented the keynote

and he covered the topic *"How to Run a Pharma Production in a Pandemic Situation"*.

He focused on many aspects in a pandemic situation. Are companies really prepared? Is there a special pandemic team in the company?

The supply chain is a critical process for every company. Are we prepared to use different suppliers if the usual suppliers fail? What happens if transport routes are closed (roads, air traffic)?

Employees no longer work in the office, but from home. How is the return to the office organised? The quality of leadership is demonstrated by the way companies take care of their employees!

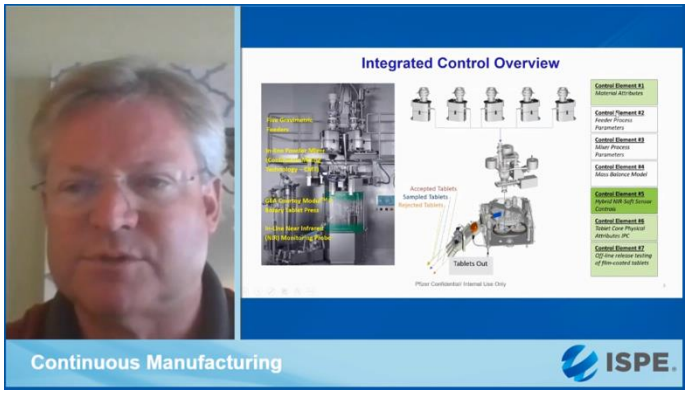
Communication with customers and suppliers is more important than ever in this situation.

Udo Vetter predicted that we can only return to previous normality after 18-24 months. By then, the new normality will be normal with all the difficulties we have to overcome.

He ended his presentation with the view: "The prepared mind will be the catalyst of change. Controlled fashioned change will be the new way. The old way will not return."

## Continuous Manufacturing has arrived at the shop floor!

John Groskoph, Executive Director, Global CMC at Pfizer, showed very well how virtual presentations can be optimally designed. In his presentation on continuous manufacturing, he used videos and good visualizations to convey his ideas. He used a manufacturing unit to demonstrate how continuous manufacturing can work today.




What did we learn during the presentation?

Continuous Manufacturing has already arrived at the manufacturing stage and can be applied –there are no excuses not to do it. Let's get down to business!

The presented project started in 2016. Today, the resulting commercial facility has been inspected several times by authorities.

## Panel discussions are big benefits in virtual conferences.

Some quotes from international regulators, who gave insights into their work and expectations in pandemic times:

"We were surprised and a little disappointed about the reaction of the industry."

"It is crucial to improve the remembrance on these experiences we made in the last months. In future we should be better prepared."

Another opinion was that "nobody was well prepared on this situation. We never

expected to be impacted on all areas we have to handle and to have a world-wide knock-down."

"A plus point for industry was the great effort to find treatments and vaccines for the coronavirus. We can say that industry and regulators step up to bring products on the table."

"It is not over yet and there are still challenges in front of us."

"PIC/S is very important and an opportunity for the collaboration of regulators."

"There will be an impact on the cost for medicinal drug products – will the patients pay for this cost increase?"

## Distant Assessment and remote GMP inspections

Another highly interesting panel discussion focused on distant assessments and remote GMP inspections. The participants represented EMA, France, UK, PIC/S, Germany, Switzerland, Australia, Italy, Russia.


It's not possible to summarize this one-hour discussion in a post. Some important outcomes are:

- We need harmonization of remote inspection!
- There is a need for guidance (for authorities and industry)!
- Terminology is a key to discuss the same issues!
- How do we ensure mutual trust?

Monika Mayr announced that EMA prepared a guideline on that topic. Many participants see hybrid inspections as a possible solution.

## Summary

Virtual conferences can be innovative if the possibilities are fully exploited. In many cases, both the organisers and the speakers have yet to embrace these formats. The longer the pandemic lasts, the more improvements we will see in the exchange of knowledge. It is to be hoped that the good of the new will be preserved.

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