

# PDA Letter

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## PDA Responds to the Novel Coronavirus Situation

Richard Johnson, PDA President

Like me, you have probably been monitoring the developing novel coronavirus situation. We are all worried about the impact to our families and our communities. We are especially concerned about those whose health has been impacted, and all whose daily routines are being disrupted. Every day, we are busy checking the latest updates, so that we can assure we are taking appropriate steps to safeguard the health and safety of our global members and staff.

Our community has a unique challenge; while we are protecting ourselves and our community, many of you have the responsibility to continue to provide critically needed healthcare products. On behalf of PDA, we want to thank you for your efforts!

Some of the actions that PDA and our partners are taking include:

- Close and regular monitoring of the situation, adherence to recommendations from global regulatory bodies and official travel warnings.
- Rescheduling events or changing the format from in-person to virtual events.
- Accelerating the development of online and virtual training for our community.
- Implementing a pandemic preparedness plan for our global staff, including expanding our Work from Home program, and assuring accurate and timely information according to CDC and WHO recommendations.

Regarding other PDA events in the United States and Europe, we will continue to monitor the situation and make additional announcements as the conditions require. If you have any questions, please [contact us](#).

I also encourage our members to follow updates and announcements from their countries' public health agencies. WHO, EMA and the U.S. CDC, among others, are sources of additional information. A series of links are posted on the [PDA website](#).

Please continue to check the [PDA website](#), PDA Connector email, [news uPDAtE](#) and [PDA Letter](#) for further information about the impact of COVID-19 on PDA activities. 🍷



### COVID-19 Resources

For updates on the COVID-19 crisis, please visit the PDA website ([www.pda.org](http://www.pda.org)).

PDA also recommends the following resources:

- World Health Organization (WHO) – Novel coronavirus (2019-nCoV) outbreak
- European Medicines Agency (EMA) – Novel coronavirus

2020 PDA EUROPE

# Quality and Regulations Conference



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2020 PDA EUROPE

# BioManufacturing



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# Berücksichtigung der Bedürfnisse von PDA-Mitgliedern in Europa

Sehr geehrte europäische PDA-Mitglieder, als Geschäftsführer und Vice President der PDA Europe freue ich mich, Ihnen diese erste europäische Ausgabe des *PDA Letter* vorstellen zu dürfen.

Wir verfolgen dabei das Ziel, den spezifischen Bedürfnissen der europäischen PDA-Mitglieder noch besser gerecht zu werden. Wir kommen aus verschiedenen Ländern und sprechen unterschiedliche Sprachen, doch im Grunde vereint uns alle das gemeinsame Ziel, das unsere Organisation prägt: die Unterstützung der pharmazeutischen und biopharmazeutischen Industrie. Dies könnte nicht besser durch das Motto der PDA zum Ausdruck gebracht werden: Connecting People, Science and Regulation®.

Die COVID-19-Pandemie hat auch auf unsere Aktivitäten weitreichenden Einfluss. Bislang mussten jedoch noch keine Veranstaltungen abgesagt werden. Für alle ursprünglich im Frühjahr geplanten Veranstaltungen konnten neue Termine im Herbst gefunden werden. Das trifft beispielsweise auf das *Visual Inspection Forum* (19-20 Oktober, Berlin) und die zugehörigen Trainingskurse (21-22 Oktober) zu.

Die im Sommer geplanten Konferenzen *Quality and Regulations Conference* (09-10 Juni, Dublin), *Virus Forum* (22-23 Juni, Brüssel) und *Advanced Therapy Medicinal Products* (24-25 Juni, Brüssel) sowie die zugehörigen Trainingskurse werden als virtuelle Veranstaltungen durchgeführt. Dabei werden die Teilnehmer die Möglichkeit der Interaktion mit den Sprechern haben. Digitale Ausstellungen und Posterpräsentationen werden das Spektrum bereichern. Wir verstehen dies als eine Chance, moderne, digitale Veranstaltungskonzepte und neue Formate zu etablieren, die in der einen oder anderen Form auch nach Aufhebung der Reisebeschränkungen Bestand haben werden.

In der zweiten Jahreshälfte beinhaltet unser Programm einerseits die bereits bekannten Konferenzen *BioManufacturing* (22-23 September, Dublin) und *Pharmaceutical Freeze Drying Technology* (24-25 September, Dublin). Andererseits möchten wir zwei neue, vielversprechende Konferenzen vorstellen. *Medical Devices and Connected Health* (08-09 September, Madrid) wird die Entwicklungen im Bereich der Medikamenten-Verabreichungssysteme im digitalen Zeitalter thematisieren. Mit der Konferenz *Aseptic Animal Health* (20-21 Oktober, Den Haag) bieten wir ein Forum, das sich den spezifischen Herausforderungen bei Entwicklung, Herstellung und Testung von Tierarzneimitteln widmet.

Zusätzlich werden diverse Trainingskurse, Interest Group Meetings und Chapter Events stattfinden.

Bei allen Konferenzen werden wir uns den Themen Nachhaltigkeit und Umweltschutz annehmen. Damit sehen wir uns in einer Vorreiterrolle bei der Diskussion der Verantwortung der pharmazeutischen Industrie für Ökologie und globale Fragen.

Ich sprach bereits vom *Visual Inspection Forum*. Das diesjährige Konferenzmotto lautet passenderweise „Innovations in Automated Visual Inspection“. Tatsächlich eröffnen automatisierte Prozesse und die künstliche Intelligenz neue Möglichkeiten bei der optischen Kontrolle; gerade auch in Situationen, in denen einer kontinuierlichen Versorgung mit Arzneimitteln besondere Bedeutung zukommt.

Mit den europäischen Ausgaben des *PDA Letters* sollen auch zukünftig die Sichtweisen und Themen der europäischen Mitglieder beleuchtet werden. Dazu möchte ich Sie bitten und ermutigen, uns Ihre Anregungen, Wünsche oder Fragen mitzuteilen. Weitere Information über Aktivitäten der PDA finden Sie unter [www.pda.org](http://www.pda.org). Besuchen Sie doch auch einmal unseren Twitter-Kanal ([https://twitter.com/PDA\\_Europe](https://twitter.com/PDA_Europe)). Wir würden uns freuen, auch auf diesem Wege mit Ihnen in Kontakt zu treten. 🍷



Falk Klar, PhD



Falk Klar, PhD

## Addressing the Needs of PDA Members in Europe

As General Manager and Vice President of PDA Europe, I welcome you to the inaugural issue of the European edition of the *PDA Letter*.

PDA hopes this issue supports the needs of our many members across Europe. We all come from different countries and may even speak different languages at home. We are connected by one common goal: supporting the needs of the pharmaceutical community by connecting people, science and regulation®.

The COVID-19 pandemic has impacted many of our activities. So far, no events have been cancelled. All events originally planned for spring 2020 have been rescheduled to autumn this year. This applies, for example, to the *Visual Inspection Forum* (19–20 Oct., Berlin) and the related training courses (21–22 Oct.).

The conferences *Quality and Regulations* (9–10 June, Dublin), *Virus Forum* (22–23 June, Brussels), *2020 PDA Europe Advanced Therapy Medicinal Products* (24–25 June, Brussels) and associated training courses scheduled for summer will be held as virtual events. Attendees will have the opportunity to interact with presenters. Digital exhibitions and poster presentations will enrich the event experience. We consider this an opportunity to establish modern concepts and new event formats, which will remain after coronavirus travel restrictions are lifted.

In the second half of this year, we look forward to meeting at established conferences *BioManufacturing* (22–23 Sept., Dublin) and *Pharmaceutical Freeze Drying Technology* (24–25 Sept., Dublin). In addition, have launched two new European conferences. The conference *Medical Devices and Connected Health* (8–9 Sept., Madrid) will reflect developments of drug application devices in the digital era. For the first time, PDA Europe will organize the conference *Aseptic Animal Health* (20–21 Oct., The Hague) which will tackle specific challenges related to the development, manufacturing and testing of aseptic veterinary medicinal products.

Furthermore, there will be numerous training courses, interest group meetings and regional chapter events throughout the year.

All conferences will cover sustainability and environmental problems, bringing PDA to the forefront of discussing preservation of the environment in the pharmaceutical industry.

I mentioned the *Visual Inspection Forum* above. The focus topic of this year's conference is "Innovations in Automated Visual Inspection." Artificial intelligence and automated processes might enhance visual inspection, which is of particular importance in situations requiring a steady drug supply.

The purpose of this edition of the *PDA Letter* is to address the needs of our European membership. I encourage you to let us know how we can further assist you. You can learn more at the PDA website: [www.pda.org](http://www.pda.org). In addition, PDA Europe is on Twitter ([https://twitter.com/PDA\\_Europe](https://twitter.com/PDA_Europe)) and we are more than happy to connect with you there! 🍷



2020 PDA EUROPE

# Medical Devices and Connected Health

Digital Products Development & Commercialization



**8-9 SEPTEMBER 2020**

**MADRID, SPAIN**

EXHIBITION: 8-9 SEPTEMBER

TRAINING: 10-11 SEPTEMBER

# Chapter Covers New Developments in Visual Inspection

Aidan Harrington, Senior Consultant DPS Global, and President-Elect, PDA Ireland Chapter



Visual inspection is a major topic of interest to PDA members around the world. On Nov. 22, the PDA Ireland Chapter held a one-day meeting in Kildare focused on *Visual Inspection — Requirements, Practical Implementation and Future Technologies*. The major critical takeaways from the event cover manual inspections, automated inspections, regulatory developments, achieving zero defects for visible particles, new technologies and difficult-to-inspect products.

## Manual Inspection

To meet the requirements for inspector training and qualification, separate defect sets for training, size sensitivity and qualification need to be created. The manual baseline should consider inspection conditions (e.g., station, lighting), inspector technique (e.g., pacing), individual inspector variability and person-to-person variability. When multiple container types, sizes and fill levels are used in a manufacturing facility, it may be possible to develop a bracketing approach to operational challenge sets. Acceptance criteria for manual inspection qualification criteria is strongly influenced by qualification set design.

The first step in developing a validation challenge set is to complete a risk assessment for the entire process, including component manufacturing — container, stoppers, product formulation, con-

tainer filling and container handling for example. A well-designed challenge set will ensure that automated processes are robust, and that defect detection is reliable. Including hard-to-detect defects in sets results in lower acceptance criteria.

Lower acceptance criteria should not be confused with lower process capability, however. Clear and detailed descriptions of created defects need to be included in procedures to ensure consistency over time and the ability to replace defects (e.g., written descriptions, pictures). If the created defect is not a direct copy of the natural defect, performing studies that demonstrate comparable performance for visual inspection should be considered. Having a specialized group or specially trained individuals devise studies would produce clear benefits.

## Automated Inspection

With the advances in technology, many companies are exploring automated inspection. To implement an automated system, though, first requires developing a high level of competence with manual inspection. Having a thorough understanding of the product and its inherent variability is required before it can be migrated from manual to automated visual inspection. For example, a company would need to develop in-house expertise in machine vision, or it would have to rely on vendor support and availability.

Should it come to selecting a vendor, having a formal process in place for commercial bid analysis allows for visual and transparent decision-making. It would also align with the desired values and culture of lean, enabling teams to emphasize a project's value to its stakeholders. One speaker relayed how one company took to the road, delivering samples door-to-door to mitigate the impact of shipment in causing sample defects. To limit potential false rejects due to container variability, Schott created vials with dimensions at limit of specifications (maximum, minimum and nominal) for heel radius, shoulder, push-up and bottom thickness.

Qualification maintenance was also discussed as an alternative to requalification with defect panels in an annual review process. This would only be valid if a robust inspection lifecycle process, per *USP <1790> Visual Inspection of Injections*, was followed (1). Trending of rejects over time is key: If an automated inspection method is shown to be better than the manual method, does this call into question the use of the manual method for reinspection?

Also having the capability to conduct off-line investigations, that is, a mirror copy of a vision system on an offline laptop, was highly recommended.

## Regulatory Developments

Defects remain one of the Top 10 reasons



for drug product recalls with more than 200 incidents since 2008. From the regulators' perspective, if you can see it, you should control it!

The quality risk management (QRM)/ lifecycle approach is the key to particulate matter control — what presents a risk to patients?

Not only equipment and processes, but the human factor should be considered. Limitations and stressors should be addressed as part of the operator qualification program, which should also include fatigue studies. And QRM processes should be integrated as part of operator training.

### Achieving Zero Defects for Visible Particles in Parenterals

When it comes to the topic of achieving zero defects for visible particles, PDA is involved in numerous activities. One study, initiated in 2017 by an industry cross-functional group (co-sponsored by PDA and the Pharmaceutical Manufacturing Forum), that addresses particle sources in pharmaceutical products is ongoing. Another task force is focusing on visible particles in ready-to-fill, use-and-sterilize components, glass and elastomer components and secondary packaging associated with packaging components. Outcomes from some of the studies to date have been published in the *PDA JPST* and publication of future results is anticipated.

### New Technologies

The industry is rapidly evolving with respect to its manufacturing processes and advanced therapies. Inspection technologies need to evolve in parallel.

Interest in applying deep learning and artificial intelligence (AI) technologies to visual inspection is growing. Factories of the future will likely feature a vision robot unit that incorporates deep learning and AI and is integrated with factory systems. Deep learning technology will be reactive, that is, the inspection reacts to product characteristics during one batch and adapts. Continuous learning ensues from production and from operators' retraining of new defects and false rejects reduced by retraining false positives.

### Difficult-to-Inspect Products

Many of those attending this meeting work primarily with lyophilized products. For these products, particles are revealed only at the surface. Organizations have developed a consistent approach with respect to destructive testing methodology (*USP <788> Particulate Matter in Injections*) and sample sizes used for lyophilized products (2). Reconstitution is typically performed in a controlled environment using a terminally filtered diluent and mixed to obtain a clear solution. While discussed, the filtration method is not used by participants; instead, the reconstituted and filtered product is examined by microscope.

While workshop participants did not have experience with other difficult-to-inspect products, **John Shabushnig** highlighted *PDA Technical Report No. 79: Particulate Matter Control in Difficult-to-Inspect Parenterals* (3). This 2018 technical report describes best practices for difficult-to-inspect parenteral product lifecycle management, destructive testing, and trending to supplement portions of the guidance given in *USP <1790>*.

During the Q&A portions of the meeting, participants shared their experiences with foreign regulators' expectations of visual inspection. Two participants reported that Russian inspectors had expressed a requirement for a Grade D background for inspections. Chinese inspectors envisage inspection taking place in a quiet, dark room with no light, apart from the booth lighting; and, in general, they prefer automated inspection. Japanese inspectors tend to have high expectations and requirements for cosmetic defects.

All in all, the meeting proved a success! The presentations were insightful and the discussion engaging.

### References

1. U.S. Pharmacopeial Convention. General Chapter <1790> Visual Inspection of Injections. In *USP 41-NF 36*, USP: Rockville, Md., 2018. [www.usp.org](http://www.usp.org).
2. U.S. Pharmacopeial Convention. General Chapter <788> Particulate Matter in Injections. In *USP 41-NF 36*, USP: Rockville, Md., 2018. [www.usp.org](http://www.usp.org)
3. Parenteral Drug Association. *Technical Report No. 79: Particulate Matter Control in Difficult-to-Inspect Parenterals*; PDA: Bethesda, Md., 2018. 🍷

## PDA Who's Who

**John Shabushnig**, PhD, Principal Consultant, Insight Pharma Consulting

# Could A.I. Optimize Visual Inspection?

Andreas Gross, Syntegon

Visual inspection is a challenging stage in the pharmaceutical manufacturing process. This is especially true for products with difficult characteristics, such as highly viscous parenteral solutions where air bubbles cannot be completely eliminated, making it problematic to differentiate them from particles. Those cases usually require long development and optimization times for vision algorithms before achieving a balanced operational level of detection versus false reject rates.

Artificial Intelligence has the potential of shortening this development period and optimizing the desired results more quickly—a classic win-win situation for both pharmaceutical manufacturers and patients, who ultimately receive high-quality products.

There are many successful automated inspection techniques on the market that enable very high detection rates, such as individual spin units to prepare the product before inspection, high resolution digital cameras and the static division light transmission method. Nevertheless, in some cases the combination of dense solutions with small containers does not promote the movement of particles, which leads to reduced detection probability. Moreover, agglomerations or other types of inherent morphological features that are similar to particles and bubbles resembling glass particles can cause false rejection of good containers. And every single false reject is one too many, particularly for high-cost products. A.I. applications have the potential of further increasing detection rates and decreasing the number of false rejects in difficult products like dense and bubbly solutions.

While many pharmaceutical producers and machine manufacturers are considering the use of A.I., reservations about implementation and validation are keeping most companies from using these applications in real production environments. In parallel, machine vision software com-



Photo courtesy of Syntegon

panies are already offering deep learning vision tools as part of their portfolio. Hence, it is not always necessary for manufacturers of automated vision inspection machines to develop their own deep learning algorithms or neural networks. In fact, the existing solutions only require moderate software modifications. Additionally, an upgrade of the vision computers with higher processing power can be realized with graphic processing units (GPUs), which are widely available in the gaming industry.

When it comes to validation, in contrast to many other industries, the deep learning model must be “frozen” once the development phase is finalized. It must be static and can no longer change to make it version-controlled for validation. A recent discussion paper published by the U.S. FDA about the regulatory framework for Software as a Medical Device (SaMD) provides a good reference for application in areas different from pharmaceutical production (1).

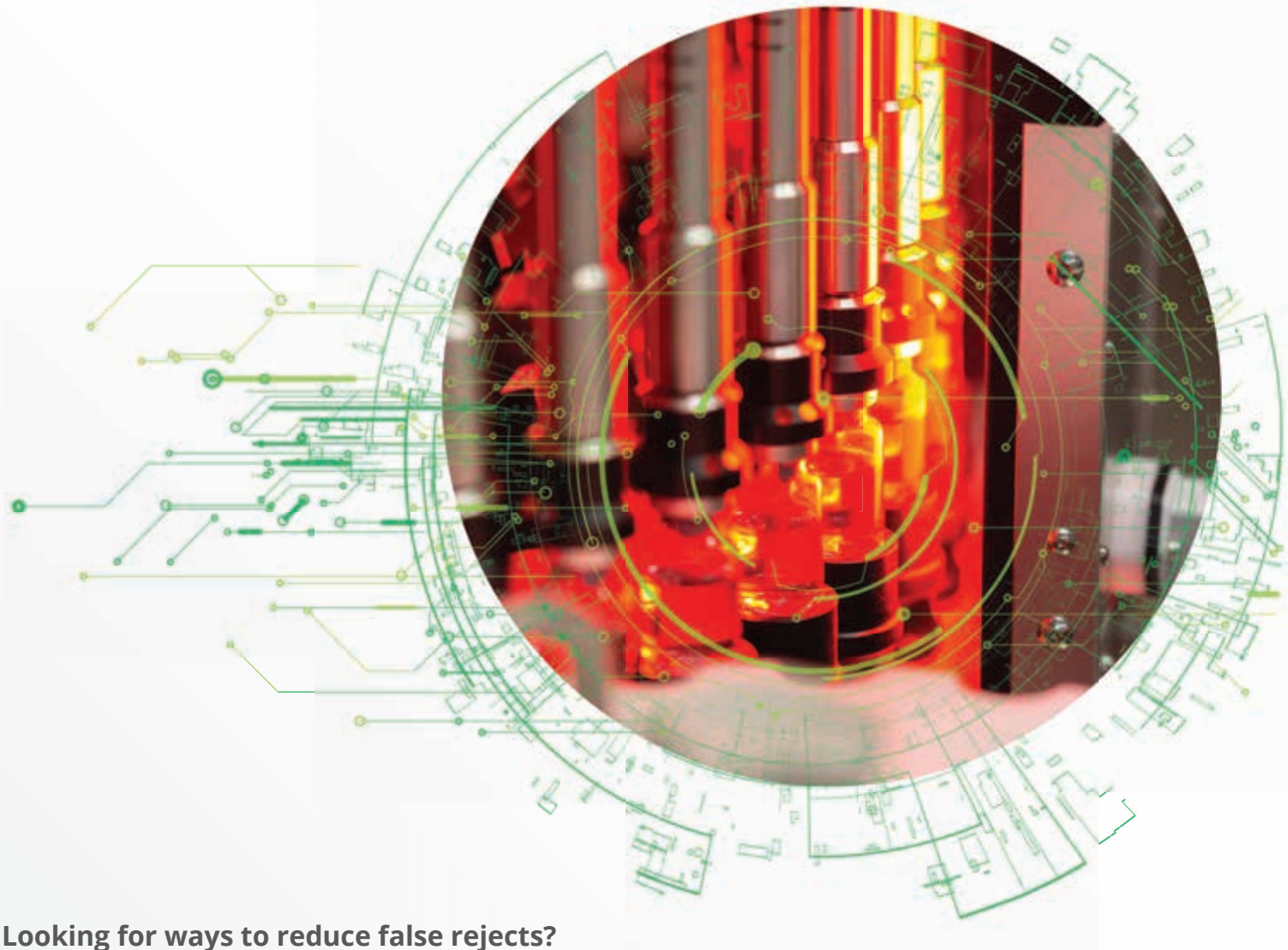
## No “One-Size-Fits-All” approach

Typically, a one-size-fits-all approach will

not work when using deep learning for visual inspection. Instead, the first step should consist of a preassessment based on a large number of diverse images from reference samples. For example, this could be images of good units with bubbles, different stopper positions, products and fill volumes for body inspection and various types of particles intrinsic to the process. Based on the available image data, offline verification studies provide the basis for the integration of deep learning models into the existing software. In the second step, a customer-specific project should be defined with parameters such as product, existing machinery, expectations and timeline.

**Figure 1** compares the standard recipe development and validation (left) to the deep learning method (right): the principle process does not change, and the recipe parameters are still validated according to GMP requirements. The only changes are the tool used to develop the process and the required hardware. As mentioned above, even the hardware only changes slightly: Deep learning requires PCs with GPUs capable of processing complex and massive amounts of data. In a determin- ➤

# Unlock the potential of AI and benefit from enhanced visual inspection performance

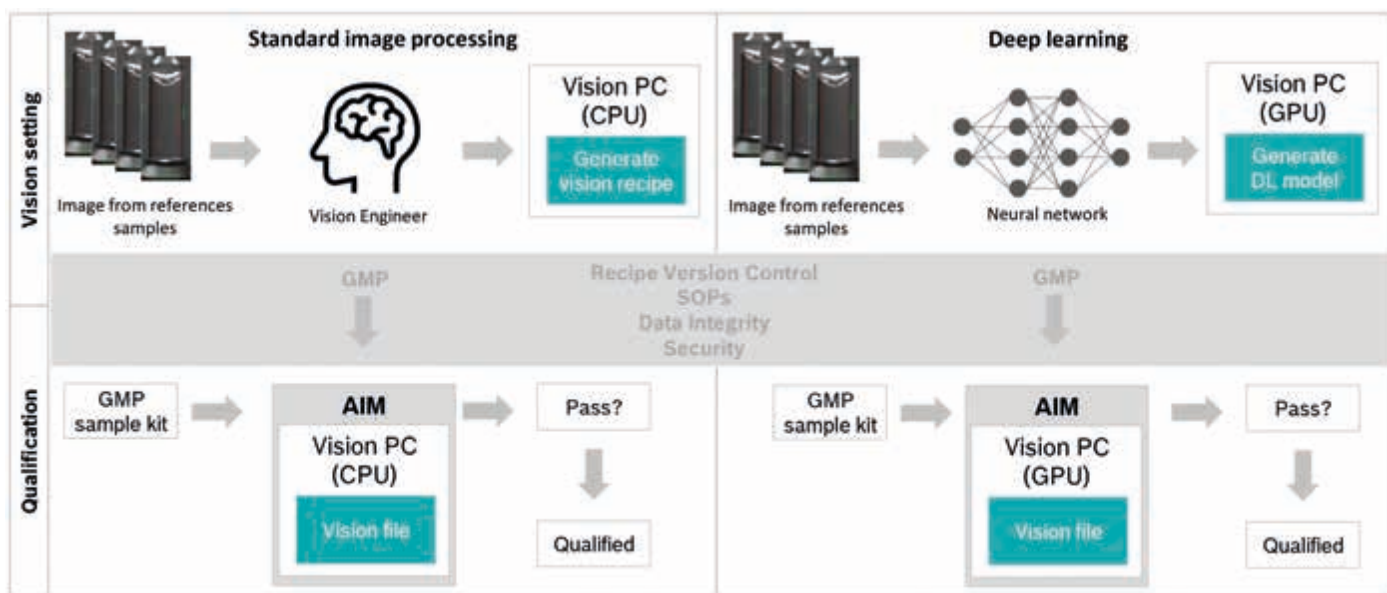


## Looking for ways to reduce false rejects?

At Stevanato Group we can support you with the most advanced developments in visual inspection integrating Artificial Intelligence. Contact us to discover how you can decrease false rejection rates by 95%\*

\* False rejects due to misclassification of air bubbles as particles.  
Source: Stevanato Group tests on a machine featuring deep learning algorithms.





Reference: Deep Learning Development and Qualification in Automated Vision Inspection Technology for Parenteral Pharmaceutical Drug Products / Jorge Delgado, Amgen Manufacturing Limited

**Figure 1** Standard and Deep Learning image processing  
*(Deep Learning Development and Qualification in Automated Vision Inspection Technology for Parenteral Pharmaceutical Drug Products / Jorge Delgado, Amgen Manufacturing Limited)*

istic deep learning model, small packages are trained up to a certain “level of intelligence” and then frozen. This is especially important regarding validation, regulatory approval and inspection.

**A.I. a Potential Trendsetter**

USP <1790> Visual Inspection of Injections specifies that “validation of the automated inspection equipment should be based on comparison with the compendial manual inspection process with an expectation that alternative inspection methods demonstrate equivalent or better performance.” This is definitely true for the current state of deep learning in visual inspection. A.I. could potentially become a trendsetter for the pharma industry as it improves the current practice of visual inspection.

“ **A.I. could potentially become a trendsetter for the pharma industry** ”

**Reference**

1. “Proposed Regulatory Framework for Modifications to Artificial Intelligence/ Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD).” U.S. FDA, Nov. 5, 2019 <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device>

**About the Authors**

**Andreas Gross** is a Global Product Manager at Syntegon. He has more than ten years of experience in the processing and packaging industry. 🍷



# PDA Enters 2020 en una nota fuerte

Como nueva presidenta de la junta directiva de PDA, espero que estéis preparados para el nuevo año y estéis entusiasmados para ver lo que PDA te proporcionará para ayudaros en vuestro trabajo diario.

Para ofrecerte un valor efectivo, nos centraremos en la agilidad, la simplificación y la innovación; éstas serán las palabras clave para nuestras actividades en 2020.

Dicho esto, como siempre, todos nuestros productos estarán basados en la ciencia e incluirán la gestión de riesgos de calidad (QRM) siempre que sea posible.

Tenemos muchas actividades previstas para 2020. A continuación se muestran algunas de los que podrían ser de interés:

- Organizaremos varias conferencias en Asia durante 2020 siguiendo el exitoso lanzamiento de nuestra nueva oficina Asia-Pacífico en Singapore el año pasado.
- Seguiremos centrandó la atención en alentar a los jóvenes profesionales a que participen en la PDA, incluyendo su participación en nuestros equipos y tareas
- Seguiréis recibiendo publicaciones de calidad, incluyendo PDA Research, Points to tables Papers, Technical Reports y ANSI Standards
- Ahora se ofrecerán cursos de aprendizaje electrónico adicionalmente a nuestros reconocidos cursos presenciales en el Instituto de Capacitación e Investigación de la PDA en Bethesda, Md.
- Continuaremos realizando investigación aplicada apoyando iniciativas de la industria
- Trabajaremos con nuestros socios regulatorios globales para fomentar el apoyo a tecnologías e innovación eficientes.
- Seguiremos promoviendo la armonización, la simplificación, la eficiencia y la aplicación práctica a nivel mundial fundamentándonos en la ciencia, la tecnología y el riesgo; y seguiremos formulando observaciones sobre los proyectos de reglamentación más relevantes basándonos en ciencia y en la evaluación del riesgo para ayudar a alcanzar los mejores requisitos científicos siempre basados en la medida del riesgo para el beneficio del paciente.

Permaneced atentos al contenido del sitio web de PDA para estar informados sobre estos proyectos e iniciativas tan interesantes

2020 será un año muy activo. Os animamos a que nos ayudéis a alcanzar nuestros objetivos trabajando activamente con nosotros, porque ambas manos son necesarias; el equipo de PDA son una de las manos y nuestros voluntarios constituyen la otra mano, ambos necesarios.

Podéis uniros a uno de nuestros capítulos o grupos de interés y participar activamente en estas actividades; también podéis escribir un artículo para la PDA Letter o PDA JPST, participar en un grupo de trabajo para la evaluación de puntos a considerar en artículos o informes técnico, o dando soporte en un comité de planificación para nuestras conferencias.

Vuestra participación active en nuestra comunidad, ayudaréis a construir la familia PDA que ofrecerá su apoyo a la agilidad, la simplificación y la innovación dentro de nuestra industria. 🍷



Jette Christensen, Novo Nordisk

## Editor's Note

The English version of Jette Christensen's message is available on the PDA Letter website



Jette Christensen, Novo Nordisk

## Le PDA débute l'année 2020 en force

En tant que nouvelle présidente du Conseil d'Administration de la PDA, j'espère que vous êtes prêts pour cette nouvelle année et impatients de découvrir ce que la PDA proposera afin de faciliter votre travail au quotidien en 2020.

Afin de vous apporter une véritable valeur ajoutée, nous allons nous focaliser sur la souplesse, la simplification et l'innovation – les mots-clés de notre action en 2020.

Cela étant dit, comme toujours nous nous appuyons sur des fondements scientifiques pour tous nos produits, et la gestion des risques qualité (QRM) sera intégrée dans la mesure du possible.

Le PDA a établi un programme de démarrage ambitieux pour cette nouvelle décennie avec un ensemble d'activités et de produits. Voici quelques exemples qui je crois seront de nature à intéresser nos membres:

- nous envisageons de tenir plusieurs conférences en Asie sur toute l'année 2020 et ce, à la suite du lancement l'année passée de notre nouveau bureau Asie-Pacifique à Singapour,
- nous poursuivrons nos efforts afin d'encourager les jeunes professionnels à adhérer au PDA, incluant la participation à nos groupes de travail,
- vous continuerez à recevoir des publications de qualité incluant les articles *Points to Consider*, les rapports techniques, et les normes ANSI,
- des formations en ligne seront maintenant proposées, en plus de nos fameuses formations offertes au *PDA Training and Research Institute* à Bethesda au Maryland,
- nous poursuivrons nos activités de recherche appliquée afin de soutenir les initiatives de l'industrie,
- nous travaillerons avec nos partenaires de réglementation à l'international pour soutenir les technologies et innovation efficaces,
- nous continuerons à prôner harmonisation globale, simplification, efficacité et pragmatisme en s'appuyant sur les fondements scientifiques ; nous continuerons aussi à commenter les projets de normes et réglementations en s'appuyant sur la science et l'analyse de risques afin d'obtenir des exigences basées sur ces principes, le tout au bénéfice des patients.

Pour plus d'information sur ces intéressants projets et initiatives, gardez un œil sur le site web du PDA.

L'année 2020 sera une année chargée. En conséquence, nous vous encourageons à participer à la réalisation de nos objectifs en engageant avec nous. Le volontariat est nécessaire, aux côtés du management et du personnel du PDA.

Impliquez-vous en adhérant à l'un de nos chapitres ou groupes d'intérêt. Vous pouvez aussi écrire un article pour le *PDA Letter* ou le *PDA JPST*, vous impliquer dans un groupe de travail pour les articles du *Point to Consider* ou un *technical report*, ou nous aider à l'organisation d'une de nos conférences en siégeant à un comité de planification.

En étant actif dans notre communauté, vous contribuerez à développer la famille du PDA qui soutiendra souplesse, simplification et innovation dans notre industrie. 🍷



2020 PDA EUROPE

# Visual Inspection Forum



**NEW DATE AND VENUE!**

The Event will take place  
at the Steigenberger Hotel Berlin,  
Los Angeles Platz

**19-20 OCTOBER 2020**

**BERLIN, GERMANY**

EXHIBITION: 19-20 OCTOBER

TRAINING: 21-22 OCTOBER