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# OPHTHALMIC DRUGS: PATHWAY TO OVERCOME PRIMARY PACKAGING AND DRUG PRODUCT MANUFACTURING CHALLENGES

In the second in a series of two articles, Rainer Glöckler, Chief Technical Officer, swissfillon, Carole Delauney, Director Business Development, swissfillon, Nicolas Eon, Senior Technology Development Manager, Terumo Pharmaceutical Solutions, and Katsuyuki Takeuchi, Associate Product Manager, Terumo Pharmaceutical Solutions, discuss the myriad complexities of developing drug products for intravitreal injection, and how the partnership between swissfillon and Terumo can ease and accelerate these products to market. The first article, published in April, covered how swissfillon's state-of-the-art filling line meets the complex requirements of ophthalmic drug products.

With the trend towards personalised medicines, there is a growing demand for highly complex drugs to treat a wide variety of diseases, each with a relatively small number of patients. In the case of injectables, highly flexible production filling lines are needed for different categories of drugs which will be ultimately presented in combination with tailored primary packaging. This could include vials, prefilled syringes and cartridges, which may then be assembled into medical devices such as pens, wearable devices or autoinjectors. These drug products (DPs) require a high level of process know-how and state-of-the-art technologies.

Advanced DPs with a small to mid-size annual demand (fewer than 500,000 units) and innovative containers and devices pose a major challenge to existing manufacturing business models based on large throughputs. The regulatory requirements for the DP in combination with the medical device are particularly stringent in the case of ophthalmic products, and must be fully understood before a product can be brought to market. By working together, swissfillon and Terumo Pharmaceutical Solutions are exceptionally well positioned to provide innovative DP manufacturing solutions to satisfy previously unmet market and patient needs.

## OVERVIEW OF THE OPHTHALMIC MARKET FOR RETINAL DISORDERS

The ophthalmic drug market can be broken down into segments based on therapeutic area. The largest sector in terms of market share is retinal disorders, which are responsible for some of the most common causes of blindness in the world, including:

- Diabetic retinopathy – the most common cause of blindness in the working-age population of industrialised countries
- Age-related macular degeneration (AMD) – the third most common cause of blindness in the world
- Retinopathy of prematurity – a notable cause of blindness in children in middle-income countries
- Retinal vein occlusion.

Retinal disorders are caused partly by over-production of a protein called vascular endothelial growth factor (VEGF) and are treated with anti-VEGF drugs, which are administered by intravitreal injection into the back of the eye. AMD may recur after anti-VEGF treatment, and require multiple rounds of treatment (once every two months).

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"The use of ophthalmic injections is increasing, but it is extremely challenging to develop the necessary very low dose syringes which are silicone-oil free, and which need to be filled to an extremely high level of precision, while minimising the presence of particles and bubbles."

The global ophthalmic drug market is forecasted to grow from US$28.4 billion (£20.5 billion) in 2020 to $36.2 billion in 2025, and to reach $47.6 billion by 2030. In 2020, retinal disorder drugs accounted for the largest share of the market, with sales of $13.1 billion and 46% market share.[1] Growth in the market will be driven by the rapidly ageing global population, the increasing prevalence of diabetes and ocular diseases, unmet clinical needs in many disease areas and economic growth resulting in increased demand in developing countries, particularly in Asia. At present, North America and Europe together make up 68% of the global market.

The most common drugs for retinal disorders are Regeneron's Eylea (aflibercept) and Genentech's Lucentis (ranibizumab) and Avastin (bevacizumab). Eylea accounted for 62% of the retinal disorder drugs market in 2020, replacing Lucentis as the ophthalmic pharmaceutical product with the greatest revenue. OSI Pharmaceuticals' Macugen (pegaptanib) and Bausch & Lomb's Visudyne (verteporfin) also continue to be used to a lesser extent. The patent for Lucentis will expire in 2022, and Eylea's patent will expire in 2025 in Europe. The opening up of the market to biosimilar drugs once patents expire represents a major opportunity for new players wishing to enter the sector. There is already interest from biotech companies in producing biosimilars, not only in Western Europe and the US, but also in Eastern Europe and Asia. At the same time, a number of pharma companies are working on next-generation ophthalmic formulations.

The R&D pipeline for drugs to treat retinal disorders also includes new classes of therapeutic agents. It is likely that the dominance of blockbuster products will diminish as medicines become more focused, and the potential growth in ophthalmic drugs will be driven by innovative products developed by biopharma companies.

## SPECIFIC REQUIREMENTS AND COMPLEXITY IN OPHTHALMIC DRUG PRODUCT MANUFACTURING

The use of ophthalmic injections is increasing, but it is extremely challenging to develop the necessary very low dose syringes which are silicone-oil free, and which need to be filled to an extremely high level of precision, while minimising the presence of particles and bubbles. The following sections discuss the key considerations for primary packaging and DP manufacturing in ophthalmic projects.

### Regulatory Requirements and Recommendations on Subvisible Particles and Endotoxins

Ophthalmic solutions should be essentially free from particles that can be observed on visual inspection. US Pharmacopeia (USP) 789 relates to particulate matter in ophthalmic solutions and describes tests for enumerating extraneous particles within specific size ranges. The ophthalmic solution is first tested by the light obscuration procedure and, if it fails to meet the prescribed limits, it must pass a microscopic procedure. Sampling plans need to be based on consideration of product volume, particle numbers historically found to be present in comparison with limits, the size distribution of particles present and variability of particle counts between units.

The US FDA has issued a Guidance for Industry[2] which specifies recommended endotoxin levels for intraocular ophthalmic devices. The recommendations specify a limit of no more than 0.2 endotoxin units per millilitre (EU/mL) for all ophthalmic viscosurgical devices.

Visible and subvisible particulates may be present in the drug formulation or may arise from the primary packaging or during the filling process. If the formulation is not stable, particulates may develop over time. The primary packaging manufacturer and the contract development and manufacturing organisation (CDMO) must guarantee that their products are in accordance with the relevant standards, and a great deal of experience and expertise is needed to minimise all possible risks. Subvisible particle testing using the light obscuration method is one of the pre-release tests carried out by Terumo for its ready-to-fill syringes.

### Use of Silicone-Oil Free Syringes to Avoid Floaters and Subvisible Particles

Silicone oil has traditionally been used as a lubricant for syringes so that the plunger can move smoothly in the syringe barrel. However, in the case of ophthalmics, it is known that silicone oil would be deposited in the eye's vitreous body after repeated

injections and cannot be evacuated.[3] Silicone-oil droplets which remain in the eye are called "floaters" and avoiding them is one of the unmet needs in ophthalmic injection treatments. There are recent studies which recommend the use of silicone oil-free syringes for intravitreal injections to address this concern.[4]

In addition, silicone-oil droplets may react with the DP in the syringe and create subvisible particles. Studies show that silicone oil plays a role in both the denaturation of proteins, and the initiation of aggregation processes in proteins.[5,6] As soon as the protein is denatured or the configuration is changed, the efficacy of the treatment will be reduced, or it may no longer work at all. Any increase in the level of subvisible particles will also increase the risk of failing to comply with USP 789.

Technologies such as crosslinked silicone oil, baked-on silicone oil, or plasma treated silicone oil have been developed by the industry to minimise free silicone oil in drug solutions. But experience shows that even these silicone-oil layers using plasma or other treatments are not suitable for drugs that are extremely sensitive to silicone oil, and in such cases a silicone oil-free system is the only option. During the development of new formulations, it is impossible to tell in advance whether or not the drug will be sensitive to silicone oil. Pre-stability studies could be carried out, but the safest option is to use a silicone oil-free solution so that the question does not arise.

Figure 1: Terumo's PLAJEX™ 0.5 mL Luer lock silicone oil-free, ready-to-fill syringe system with i-coating™ stopper.[6,7]

These considerations are a major driver in deciding the most suitable system for ophthalmic projects. The PLAJEX™ 0.5ml Luer lock syringe is supplied silicone-oil free, with Terumo's proprietary i-coating™ lubricant on the plunger stopper (Figure 1).

## Use of Next-Generation Syringes to Ensure Safe and Easy Ophthalmic Injection

As ophthalmic injections are directly administered to the eye, it is vital to minimise the potential risks around the injection process. With the trend of injectable drug development towards more viscous formulations, and with thin needles (for example, 30 or 31 gauge) being used for ophthalmic injections, it may be necessary to apply high pressure to the syringe. One of the major advantages of using a polymer syringe is that the Luer lock and the syringe barrel are a single moulded component, known as an integrated Luer lock, such as PLAJEX™ Luer lock syringes. In the case of a glass syringe, a polycarbonate Luer lock adaptor is assembled onto the syringe, known as an assembled Luer lock, and there is a risk that the Luer lock adaptor pops off from the syringe barrel when high pressure is applied to the syringe, such as during the injection of viscous formulations.

Another advantage of a polymer syringe is the wider design flexibility, so it is possible to design syringes that are easier to handle by adjusting the inner diameter, outer diameter and length of the syringe as required for the intended use.

## Ensuring Accurate, Low-Volume Doses

Very low fill volumes are required for ophthalmic injections. The range of the fill volume is usually in the range of 100–200 µL, and filling syringes with such small volumes requires high-precision systems.

A speciality of swissfillon is that its filling line transports through syringe by syringe. This allows every syringe to be weighed using the tare and gross weigh installed on the machine, and the volume in each syringe to be calculated. Depending on the gap between the target and actual weight of the syringes, a feedback loop corrects the pump automatically. In practice, an average of three to five syringe weights is used to smooth the curve, rather than correcting for each syringe. This approach means that swissfillon can achieve exceptionally high accuracy during filling, despite such low fill volumes, and typically has an accuracy well within ±2%.

This monitoring of individual syringes is very unusual. Most CDMOs carry out nest filling, for which such a tight specification on fill accuracy is not possible. With nest filling, there is usually a 2% fully automatic in-process-control (IPC) weigh calculation, so only two out of every 100 syringes are checked. This means that any overfill or underfill will result in 50 syringes being rejected, rather than a single syringe on the swissfillon filling line.

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Filling accuracy is driven by the pump, the tubing and the filling needle. The pump is one of the most critical considerations in the filling process. A peristaltic pump has a press release mechanism and, over time, particulates may occur due to damage to the pump tubing. This must be considered when deciding how long a filling process can run, as the particulates enter the system after the filter. The process uses very specific high-quality silicone tubing, but with the pump running at around 500 revs per minute in order to guarantee that syringes can be filled within two seconds, each fast start/fast stop causes extreme stress to the tubing. For this reason, the tubing must be checked and changed if necessary after 8–10 hours' run time.

An accuracy of ±5% is usually guaranteed because fill accuracy depends to some extent on the product solution. For critical, higher risk solutions, there needs to be very well-defined accuracy. If required, improved levels of accuracy could be achieved by changing from a peristaltic pump to a rotary piston pump. Stainless steel or ceramic rotary piston pumps offer exceptional accuracy and remove the risk of particulates as no tubing is placed under stress.

## Minimising Overfill

Minimising overfill in ophthalmic prefilled syringes is a challenge. Given the very small volumes which are filled and administered, even a reduction in the filling volume of 10–20 µL will have a significant impact in percentage terms.

Typically, only a third of the filled DP is injected into the eye – in other words, syringes are overfilled by a factor of three in order to guarantee the expected administration volume. Two-thirds of the DP is wasted due to the hold-up volume (dead space) of needles and syringes, the priming process for expelling air bubbles from the syringe and overfilling to address variation in the filling process. For example, in the case of Lucentis, syringes are prefilled with 165 µL but only 50 µL are injected. Some wastage is unavoidable – even with extremely thin needles, there will be residual drug inside the needle, needle hub, and syringe Luer bore – but it is important to ensure that residual drug in the needle and syringe is minimised.

Wastage due to overfilling is extremely costly for pharmaceutical companies in the case of both ophthalmic drugs and other very expensive DPs. By working together, the syringe manufacturer and filling company can reduce overfill and thereby achieve significant savings for the client. The primary packaging has an important role to play because overfill is necessary not only to compensate for any variation of the filling process, but also to allow for any variation in the dimensions of the primary packaging.

## Bubble-Free Filling

Bubble-free filling, the stoppering process and minimised overfill are all closely connected. For medical devices which require an exact injection volume, the precision will be higher if bubbles are minimised, however, in the case of ophthalmics, marketed products are known to present quite a large bubble (i.e. head space air). Any air in the syringe must be expelled before the injection can be administered, and this will result in loss of the drug substance. Even if there are no bubbles in the syringe, very small amounts of residual air may remain in the Luer bore and in the needle. If bubbles can be completely avoided, there will be no air to be removed so the overfill can be reduced, and less of the DP will be needed.

In order to achieve bubble-free filling, the stoppering process has to be adapted, and the plunger stopper must be set under quite a high level of vacuum. The stoppering process is driven by the product solution itself. If the solution is compatible with a high level of vacuum, the stopper setting is reasonably straightforward. It is always important to apply the vacuum, but this may be achieved with non-compressional stoppering or with a very short insertion tube.

Bubble-free filling may be crucial to reduce the risk of protein degradation in certain drugs. Denaturation of a protein-based product could start at the fluid-air interface, and the formation of aggregates must be avoided so that there is no risk of aggregates entering into the eye.

A further consideration is that during transportation, the syringe can be exposed to variations in pressure. Even with road transportation, changes in altitude during the journey cause changes in pressure (particularly in mountainous regions) and this can result in lower pressure outside the syringe than inside the syringe. If this happens, and the headspace or the bubble is too big, it may induce stopper movement during transportation, and result in loss of sterility of the product.

Similarly, the sterilisation process of the syringe surface placed into a blister closed with a lid is most commonly carried out with ethylene oxide (EO), and a vacuum is applied outside the syringe during the sterilisation process. The difference in pressure results in bubble expansion, with large bubbles expanding much more than small bubbles, potentially inducing stopper movement. This means that a final sterilisation which involves vacuum can be designed more easily if the headspace is smaller.

At present, although the bubble may be reduced in the syringe, air will generally remain in the syringe Luer bore. Air in the Luer bore could be avoided by applying a strong vacuum to the empty syringe prior to filling. Vaccum filling is now being implemented by swissfillon, which allows the residual air in the system to be reduced or removed. This will help to reduce loss of the DP and will be particularly valuable in the case of oxygen-sensitive products.

## Stoppering

One of the challenges of using very small stoppers, which are necessary for 0.5 mL syringes, is that the stoppers must be correctly positioned and oriented during the transport and stoppering process on the manufacturing line in order to be correctly inserted into the syringes. The sorting of the stoppers in the bowl is very important, and therefore a high level of precision in the design of the bowl is needed to guarantee that the system runs well throughout the process. If there is a stopper which is not correctly aligned in the filling system, syringes can be lost or damaged. This means that wrongly positioned stoppers must be removed at the start of the transport system to the stoppering position (as they enter the swinger).

With small stoppers, the ratio between diameter and length means that the stoppers will be relatively longer than other stoppers. This, in turn, means that the centre of gravity of the stopper is usually higher than normal. The sorting board uses the position of the centre of gravity of the component to sort and orientate the stoppers, and to feed the stoppers into the machine, which can be much harder to achieve in this context.

The other challenge is that silicone oil-free stoppers are preferred for the ophthalmic market, in order to avoid subvisible particles and floaters in the eye, which means that silicone oil cannot be used on any of the filling machine

components. With standard plunger stoppers, there is "transport" silicone oil, and nearly all stoppers on the market have been covered with a very small quantity of silicone oil to avoid stickiness during processing. In the absence of silicone oil, the movement of the stopper in the bowl is very different, and the stoppers are not synchronised. The nature of these stopper complexities in DP manufacturing requires a high level of expertise and experience from the CDMO.

### Sterilisation

The final sterilisation of the surface of the drug-filled syringe is very important for ophthalmic drugs. There are a number of options:

- Steam sterilisation is commonly used if the product is stable enough to be heated, but this is rarely the case for ophthalmic DPs as thermal sterilisation will destroy biologically derived substances.
- EO may be suitable in some applications, but any contamination with EO passing through the packaging may damage or destroy the product inside.
- Nitrogen dioxide ($NO_2$) is a relatively new technology that may be suitable in these applications, as $NO_2$ is known to be less aggressive than other sterilisation gases and the process can be carried out in relatively low temperature.

Although the final sterilisation is not part of swissfillon's process, the fact that sterilisation will subsequently be carried out has an impact on the DP manufacturing requirements, including the need for bubble-free filling and avoiding the use of silicone oil.

It is very important that swissfillon fully understands the final sterilisation requirements for a product, as this will affect the release testing and storage. If there is too much bioburden on a syringe when it is introduced into the steriliser, the system may not be able to achieve effective sterilisation. For this reason, the final inspection is performed in an ISO 7 cleanroom, in order to guarantee a class D minimum release environment.

Another specific requirement for ophthalmics relates to endotoxins. As mentioned prior, FDA guidance recommends that there should be no more than 0.2 EU/mL for ophthalmic viscosurgical devices. This has an impact on the DP manufacturing process because if the bioburden at the end of the compounding process is too high, it will result in a higher level of endotoxins due to cells killed during compounding releasing a large number of endotoxins. This must be kept under control as only bioburden (not endotoxins) is removed by sterile filters, so there is a risk that endotoxins will be found in the syringe.

## ADVANTAGES THAT SWISSFILLON/TERUMO CAN OFFER TO MEET YOUR REQUIREMENTS

Taking into consideration the many complexities and specific requirements for ophthalmic DPs discussed thus far, a drug manufacturer can minimise risks by working with experts who have a proven track record and who are able to offer the latest technology. This will provide a much more streamlined solution than attempting to achieve each stage of the process in isolation.

Very few companies offer silicone oil-free systems, but such coating is one of Terumo's core technologies, and it has developed and applied a proprietary i-coating™ on the plunger stopper that allows for a consistent and predictable gliding force of the syringe. Terumo is confident that its advanced technologies can add value to its clients' ophthalmic projects.

A state-of-the-art filling environment has been developed by swissfillon that ensures maximum safety for ophthalmic applications. This was achieved by working from the outset with Optima (Schwäbisch Hall, Germany), a highly respected filling line manufacturer, in order to achieve exceptionally high specifications. The swissfillon technology involves a 100% automated filling process in which every glove intervention is documented, 100% tare and gross weighing to deliver high accuracy on extremely low filling volumes, and 100% stopper setting control to minimise bubbles. A speciality of swissfillon is that its filling line transports through syringe by syringe, providing exceptional accuracy and efficiency in the fill process. The company's aim is to become the global market leader in high-precision DP manufacturing, filling complex pharmaceuticals into next-generation containers and devices.

### Implementing the Technology

The key principle of the swissfillon/Terumo collaboration is readiness. Working together, the companies will do all they can to respond to customers' requirements as quickly and effectively as possible. By forming relationships and working with machine makers, they are able to pre-validate or pre-design solutions, so they can be ready when a customer chooses to implement their technology.

Having multi-use and flexible filling equipment allows swissfillon to handle complex implementations. However, one of the most critical steps is the time taken to establish a process on the filling machine. This requires discussions on the best way to work together with the customer in order to have the solution on the machine in the shortest possible period of time.

Ideally, swissfillon would like customers to get in contact eight months before the filling is due to start, and Terumo should also be included in these initial discussions in order to consider the compatibility of the packaging that can be supplied. This would allow for the optimisation of process parts at the outset and set up of the initial templates, including the stoppering process.

The discussions should consider how the rubber components will be supplied,

Figure 2: swissfillon's rapid transfer port used for ophthalmic fill & finish.

for example in a transfer bag solution, or a double sterile bag solution. It is also necessary to consider whether the rapid transfer ports (RTPs) be 110 mm or 190 mm in port diameter. One of swissfillon's strengths is that it can accept components in either a 110 mm port bag or 190 mm port bag (Figure 2). 190 mm systems allow bags to be hooked up and disconnected several times. These points have to be agreed well in advance in order to assess whether it is necessary to customise either the filling machine or the packaging of the primary container. If the manufacturer's preferred solution isn't immediately available, it may take some time to develop and validate.

swissfillon/Terumo is the right DP manufactacturing partner for you if:

- **Streamlined communication** between partners is key
- **Time is critical** from your first inquiry to delivery
- **Maximum quality and security and minimal product loss** are must-have requirements
- **Bubble-free filling and precise plunger setting** are crucial
- **Innovative silicone oil-free syringes** could reduce the risks of your drug development

Figure 3: Together, swissfillon and Terumo offer a best-in-class solution for ophthalmic projects.

## CONCLUSION

The close collaboration between swissfillon and Terumo has allowed the companies to tackle and solve the specific challenges related to ophthalmics and add value to customer projects.

There is a tendency for the industry to work in silos, which can slow down the manufacturing processes. However, once it can be demonstrated that a tiny detail in the design of a syringe can have a huge impact on the finish, then it becomes possible to optimise the overall value chain.

Time to market is often a key factor in the success of start-up companies developing biosimilars or entering the market with new DPs – and minimising time to market is one of the strengths of the swissfillon/Terumo collaboration. Early

discussions and collaboration between the drug manufacturer, the primary package manufacturer and the specialist CDMO is vital to support a project's timeline.

The companies are confident that the combination of Terumo and swissfillon will offer a best-in-class solution for ophthalmic projects (Figure 3). Their combined expertise and experience of using the technologies needed for this complex area enables them to provide support for other biologics entering the market, and offer reliable and stable solutions suitable for each product's specific requirements.

## ABOUT THE COMPANIES

**swissfillon** is a CDMO for complex injectables, providing aseptic DP manufacturing (filling) services to pharmaceutical and biotech companies. It ensures the highest quality, security and fully cGMP compliant services for high value, complex and difficult to fill products. With its innovative, fully automated and highly flexible filling line, swissfillon provides manufacturing capacity for vials, syringes and cartridges for 1–200 L batch sizes, when the product is too complex for small (manual) DP manufacturing or when the larger manufacturers are fully utilised for large quantities.

**Terumo Pharmaceutical Solutions** is a global company which offers comprehensive product design and development services, as well as a portfolio of injection, infusion, and primary packaging solutions. Terumo is trusted for quality and precision and has decades of experience collaborating with pharmaceutical companies from the earliest phases of drug development to the latest stages of product commercialisation to optimise critical aspects of parenteral drug delivery.

## REFERENCES


1. *"Global Ophthalmic Devices Market 2020-2030". Visiongain, March 2020.*
2. *"Guidance Document: Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices". US FDA, Aug 2015.*
3. *Khurana RN, Chang LK, Porco TC, "Incidence of Presumed Silicone Oil Droplets in the Vitreous Cavity After Intravitreal Bevacizumab Injection with Insulin Syringes". JAMA Ophthalmol, 2017, Vol 135(7), pp 800–803.*
4. *Olea JL et al, "Silicone Oil Droplets in Repackaged Anti–Vascular Endothelial Growth Factors for Intravitreal Injections: In Search of the Main Source of Contamination". Eur J Ophtalmol, 2020, Vol 30(4), pp 774–779.*
5. *Krayukhina E et al, "Effects of Syringe Material and Silicone Oil Lubrication on the Stability of Pharmaceuticals Proteins". J Pharm Sci, 2015, Vol 104(2), pp 527–535.*
6. *Yoshino K et al, "Functional Evaluation and Characterization of a Newly Developed Silicone Oil-Free Prefillable Syringe System". J Pharm Sci, 2014, Vol 103(5), pp 1520–1528.*
7. *Kiminami H et al, "Impact of Sterilization Method on Protein Aggregation and Particle Formation in Polymer-Based Syringes". J Pharm Sci, 2017, Vol 106(4), pp 1001–1007.*


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**Carole Delauney** is Director Business Development at swissfillon. She has 18 years' expertise in the field of CDMOs, during which she held highly technically skilled commercial positions looking for specific solutions adapted to the outsourcing needs of pharmaceutical and biotechnology companies with a focus on sterile drug product manufacturing. She holds a five-year degree in Biochemistry.

**Nicolas Eon** is Senior Technology Development Manager at Terumo. He graduated from the University of Nancy and Nantes (France) and holds a Fluid Mechanics & Energy Science Engineering degree, a master's degree in Energetics and Heat Transfer and a PhD in Biomechanics. Dr Eon worked for 10 years in the automotive safety industry where he led the system engineering department of a leading global company. Dr Eon started to build his expertise in the field of pharmaceutical primary containers 15 years ago. He held several managing positions, from product development to strategic marketing, in leading global companies that covered the full range of primary packaging, where he launched successful products on the market and built sustainable long-term strategies. Dr Eon joined Terumo Pharmaceutical Solutions in 2020. Since 2010, he has been an active expert on ISO technical committees as part of the French and Swiss delegation.

**Katsuyuki Takeuchi** is an Associate Product Manager at Terumo Pharmaceutical Solutions. With extensive knowledge in pharmaceutical science, he has worked in research and development for injectable drug products, such as IV solution bags and prefilled syringes, and contributed to launch various products onto the market. Using his experience, Mr Takeuchi currently has product management responsibilities for Terumo's polymer-based prefillable syringes platform.

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