



TRANSITIONING FROM VIAL TO SUBCUTANEOUS INJECTION DEVICES FOR BIOLOGICAL DRUG PRODUCTS

In this article, Michael Adler, PhD, Director Drug Product Design, Venkata Appa Reddy Goli, Research Fellow, Formulation and Process Development, Andrea Allmendinger, PhD, Chief Scientific Officer, and Hanns-Christian Mahler, Chief Enablement Officer, all at ten23 health, discuss the various factors that need to be considered when transferring to a delivery device for subcutaneous injection, such as a prefilled syringe or autoinjector, during clinical trials or post-launch, especially when transferring from a vial format for intravenous infusion.

The subcutaneous (SC) route is becoming increasingly important for the administration of biologics. With the development of SC injection devices, the paradigm of drug product development has continued to shift towards patient centricity by enabling self-administration and ease of use for patients, improving compliance and adherence and reducing the burden on healthcare systems.¹ The number of approved monoclonal antibody (mAb)

products has been increasing over the last few decades, with a proportional increase in the number of SC products (Figure 1), based on the information compiled by ten23 health on US FDA-approved products.

About 79 mAb products, excluding antibody-drug conjugates (ADCs), were approved between 2015 and 2023, which is twice the number of products approved between 1994 and 2014 (31 products). 41% of mAb products approved between

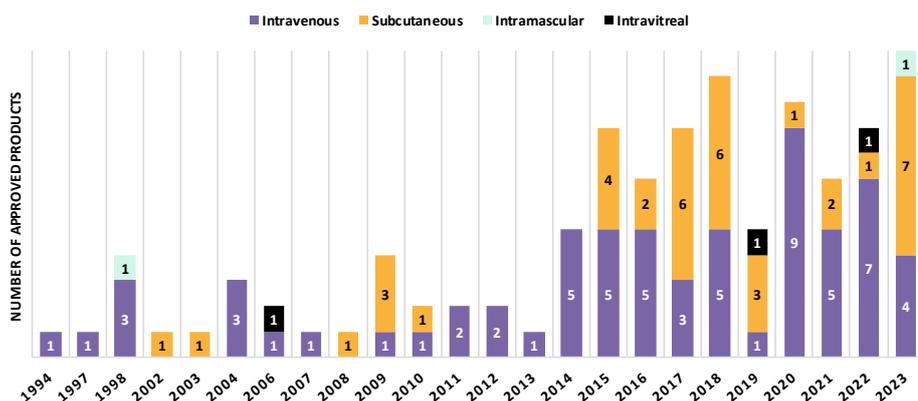


Figure 1: Route of administration of FDA-approved monoclonal antibody products.

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“41% of mAb products approved between 2015 and 2023 are administered by SC injection, whereas it was 24% between 1994 and 2014.”

2015 and 2023 are administered by SC injection, whereas it was 24% between 1994 and 2014. In 2023, an impressive number of mAb products (7 out of 12) were approved for SC administration, marking the highest number per year in the past 30 years. Numbers in other countries (e.g. EU approvals) are in line with the trend towards SC administration of biologic injectables.

As innovators change their product lifecycle management approach towards increased patient centricity, transitioning from intravenous (IV) infusion to SC administration with an injection device can be a huge game-changer (patient focus, compliance, differentiation from competitors), with notable examples being Herceptin® (trastuzumab, Roche/Genentech), MabThera® (rituximab, Roche/Genentech), Actemra® (tocilizumab, Roche/Genentech), Benlysta® (belimumab, GSK), Entyvio® (vedolizumab, Takeda) and others. There are also cases where biosimilars have been developed for SC administration when originators were solely available for IV.

Advances in the understanding of SC delivery and SC drug delivery technologies have unlocked the perceived “volume limitation” for SC administration, which have traditionally been assumed to have a maximum 0.5–2 mL injection volume. Much larger injection volumes, even up to 10 mL or more, can now be delivered subcutaneously, with 25 mL being studied in a recently published study in the absence of a permeation enhancer.²

In some cases, co- or subsequent administration of hyaluronidases (enzymes that locally and transiently digest the SC tissue) can facilitate administration of larger injection volumes by reducing SC tissue back pressure.³ Using innovative SC delivery devices, such as on-body injectors (OBIs), including West’s (PA, US) SmartDose or Ypsomed’s (Burgdorf, Switzerland) YpsoDose, can also facilitate larger-

volume SC injections without a permeation enhancing enzyme. Herceptin Hylecta™ (trastuzumab/hyaluronidase, Roche/Genentech), Rituxan Hycela® (rituximab hyaluronidase, Roche/Genentech), Darzalex Faspro® (daratumumab/hyaluronidase, Janssen) and Phesgo® (pertuzumab/trastuzumab/hyaluronidase, Roche/Genentech) are examples of SC administered drugs exceeding 2 mL using hyaluronidase co-formulations. On the other hand, Repatha® (evolocumab, Amgen) used the Pushtronex® system (West’s SmartDose®) and Ultomiris® (ravulizumab, Alexion) used West’s SmartDose® to deliver 3.5 mL of solution.

In first-in-human (FIH) clinical trials, biologics are usually administered by IV injection or infusion for various reasons, such as ensuring 100% bioavailability. Some companies already test SC delivery in FIH studies to establish SC injection early on, which saves time for non-clinical and clinical bridging later. Indeed, establishing and understanding bioavailability early during development can be essential to avoid later undesirable surprises, because bioavailability after SC administration may be low due to SC matrix and tissue interaction, depending on the molecular properties of the drug.

Vial presentations often serve the need for early clinical studies, as the dose volume can be easily adjusted for dose escalation and the development of vial presentations is less complex than for injection devices, making it less prone to technical issues that might lead to a delay of FIH clinical trials. The SC administration across different dose groups in the FIH study out of a vial would be achieved by administering:

1. Different volumes, such as using disposable syringes with or without SC clinical pumps
2. Using a placebo/diluent formulation to dilute to the respectively required concentrations and then administering similar volume, such as by using a disposable syringe with or without SC clinical pumps.

Hence, having a high-concentration formulation for SC administration is highly recommended when choosing a vial presentation for FIH clinical trials. If using a prefilled syringe (PFS) for SC administration in FIH studies, it should preferably contain the highest dose, using either additional

dose strengths (concentrations or volumes) or “down dosing” the syringe to administer lower doses (although this approach is not recommended).

Using vials for SC administration in commercial settings may also be a consideration. However, it is obvious that errors and issues with the usability of such products, such as handling vials and solution withdrawal, may present significant issues, depending on the user group. Therefore, a transition from a vial to an SC injection device is common for biologics and can occur either during clinical development or post-launch. These devices include PFSs, autoinjectors, pen injectors and OBIs.

When switching to an SC injection device, either during or after clinical trials, the following scenarios are possible:

1. IV vial to SC injection device during clinical development
2. IV vial to SC injection device post-launch
3. SC vial to SC injection device during clinical development
4. SC vial to SC injection device post-launch
5. SC injection device to SC injection device post-launch.

Moving from IV to SC (cases 1 and 2) is more complex as it includes a change of the route of administration (RoA). As the bioavailability after SC injection for biologics is less than 100%, implying a modified pharmacokinetic (PK) profile, the dose must be adapted. Knowledge about the anticipated bioavailability is therefore key. Furthermore, some drugs may have other safety and/or efficacy profiles with SC vs IV administration, depending on their mode of action. In addition, because of the smaller injection volume for SC administration compared with IV infusion, a change of formulation and container closure system (CCS) is usually required, necessitating a change in the manufacturing process.

The transition from an IV infusion or SC vial to an SC injection device requires several chemistry, manufacturing and controls (CMC) development activities, as well as clinical and non-clinical, depending on the timing and scope of the change:

- Formulation development
- Primary packaging selection and integration with formulation
- Device selection and device development
- Drug-device integration

- Drug product manufacturing process development
- Bridging studies
 - Comparative stability studies, including real-time and accelerated stress stability and characterisation
 - Non-clinical studies
 - Clinical studies.

CONSIDERATIONS FOR SC FORMULATION DEVELOPMENT

API Concentration

The increasing trend of SC administration has been accompanied by a rise in high-concentration formulations, due to the limited injection volume for SC administration. Since 2015, a notable number of high-concentration (>100 mg/mL) formulations have been approved (44%), with even higher numbers in 2023 (more than 50%). However, the use of large-volume injection products at mid-range concentrations is also on the rise, reducing some of the technical challenges related to high-concentration formulations. Generally, the higher the concentration, the greater the protein aggregation, the higher

the viscosity and the higher the concentration of potential impurities from the drug substance process (e.g. lipases), which may also impact stability. Therefore, the concentration of the API is usually a compromise between injectability, stability, manufacturability and acceptable dose volume to achieve the desired dose (Figure 2).

Selection of Excipients

Biologic formulations commonly contain a buffer system (e.g. histidine, acetate) to ensure adequate pH, a stabiliser/tonicity adjuster (e.g. sucrose, trehalose) and a surfactant (e.g. polysorbate 80, polysorbate 20 or poloxamer 188) to protect the protein against adsorption and interfacial stress. Excipients must be safe in the concentrations and doses to be administered (considering the target indications, for example, adult versus pediatric use) and acceptable for parenteral use from a safety and regulatory standpoint.

High-concentration mAb formulations frequently contain excipients such as salts or amino acids to modify or weaken protein-protein interactions, thereby lowering the viscosity while maintaining

colloidal stability. Based on ten23 health's assessments of marketed products, 26 of 48 (~55%) approved high-concentration injectable mAb products contain amino acids, including arginine, proline, glycine and methionine. Some of the high-concentration formulations also use amino acids or chelators to prevent oxidation of the API or polysorbate.

The optimal formulation pH depends on the stability and viscosity, considering tolerability in the patient population. According to ten23 health's assessment, most SC products are formulated to between pH 5.2 and 6.2, where most of the products show acceptable stability. Histidine remains the leading buffer of choice (~60%) for high-concentration mAb products, followed by acetate. Over the years, the usage of citrate as a buffer has reduced considerably for SC administration compared with the IV route, based on some (poorly studied, in the authors' view) concerns on citrate formulation causing injection pain upon SC injection. Some products initially approved with citrate buffer were re-formulated, such as adalimumab and ixekizumab. Such re-formulations may also generate intellectual property.

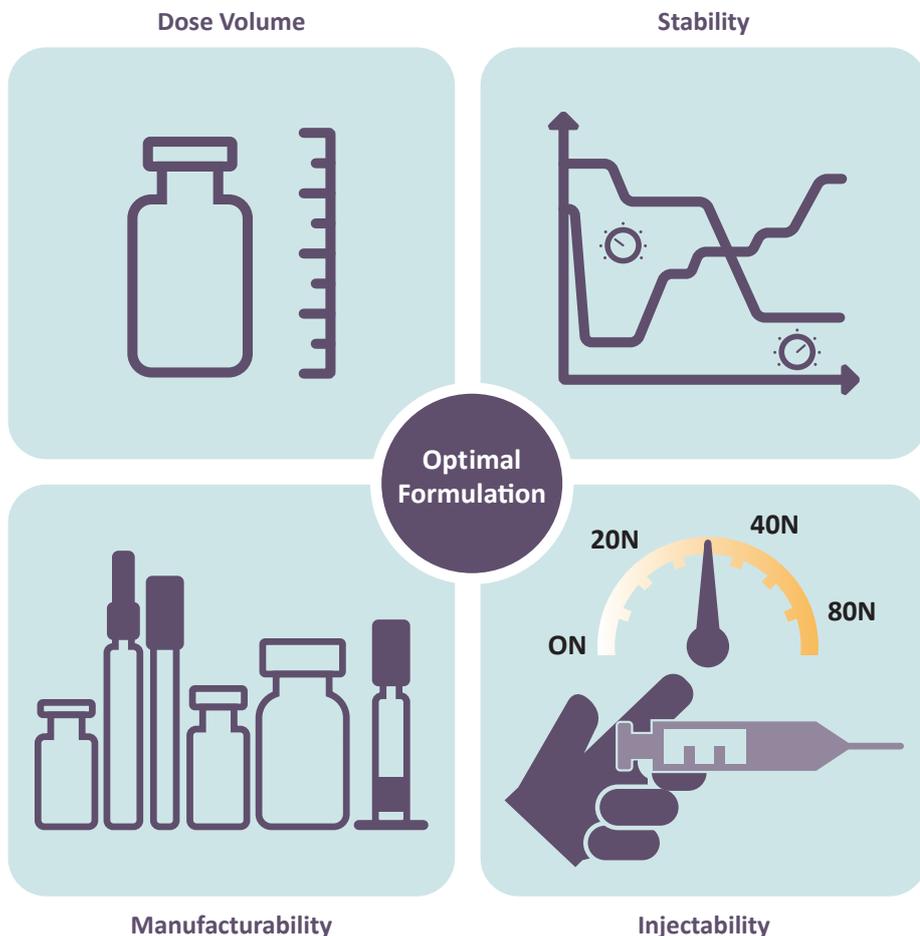


Figure 2: Interplay of critical parameters impacted by API concentration and formulation.

THE EVOLUTION OF SC INJECTION DEVICES

Injection devices represent the pinnacle of convenience for patients, enhancing comfort, adherence and overall satisfaction. These devices, typically arriving as ready-to-use products, streamline handling, eliminating the need for additional manipulation and reducing errors. Specifically designed for SC administration, they empower self-administration, facilitating the transition to at-home care settings and yielding significant economic savings. The engineering behind these devices prioritises patient needs, informed by human factors studies, to ensure optimal usability.

While traditional PFSs and autoinjectors paved the way, recent advancements include larger-volume OBIs and connected devices that enhance treatment scheduling and outcomes. This diversity in product presentation enables flexible care settings, promoting medical compliance. However, the development of injection devices presents additional technical and regulatory challenges compared with vial presentations, requiring careful consideration of drug-device integration and manufacturing,

including selection of the primary packaging and device itself. At present, vial presentations remain favoured for early-stage development, offering flexible dosing and fewer technical hurdles, with the transition to devices necessitating further consideration deeper into development. Preferably, such vial to PFS changes would not require any facility or provider tech transfers, which always add additional risk and cost, rather than being manufactured at the same line, facility and vendor, such as ten23 health.

SC INJECTION DEVICE SELECTION

When selecting an SC injection device, several critical factors must be considered to ensure optimal device performance, as well as patient safety and comfort, while also maintaining drug product stability and compatibility with the primary packaging and injection device. Firstly, the dose volume plays a pivotal role in device selection as different devices, such as PFSs, autoinjectors and OBIs, are designed to accommodate varying volumes of medication. Given that the final dose will typically be determined during clinical studies, multiple drug product presentations and strengths may be considered when developing a clinical product for SC administration.

Product viscosity and flow characteristics, such as non-Newtonian behaviour,

is another crucial factor as it directly impacts injection force, affecting the injection time dependent on needle size. According to the Hagen-Poiseuille law, a change in the inner needle diameter impacts injection time by the power of four. Thus, device components must be adequately selected and controlled to meet end-user or device requirements. The variability of viscosity, due to the API concentration, and needle inner diameter will determine the failure criteria to be assessed.

Further considerations when selecting the injection device include the selection of the primary packaging container materials, usually glass (siliconised or non-siliconised) or polymer (e.g. cyclic-olefin polymer), along with rubber (siliconised or non-siliconised) for the stopper. Material choice can impact factors such as gas permeability, which is critical for oxygen-sensitive molecules or preserved multi-use formulations where some preservatives may evaporate across plastics; device performance, including the break-loose and glide force; manufacturability; and product compatibility and stability.

In general, material variability, such as its dimensions, must be specified and controlled. This is especially important in the context of ready-to-use (RTU) components. Factors such as particle contamination, scratches and endotoxins can all be influenced by how RTU components are

produced, assembled, stored and shipped, and must be tightly controlled in order to meet requirements. Therefore, to ensure quality, the specifications for such factors should be much tighter for RTU primary packaging than those for the final product's specifications.

DRUG-DEVICE INTEGRATION

Components to consider when developing an SC injection device are the API, the formulation, the primary packaging/container closure system and the device. Their characteristics, interplay and manufacturing process may impact:

- Performance (e.g. usability, functionality, injectability)
- Protection of the product against microbial ingress
- Protection of the product against permeation of gases
- Stability/compatibility
- Safety
- Manufacturability
- Transportability.

Several technical development studies are required to address potential risks during drug-device integration (Table 1). Undertaking this process is key to optimising the design of all the components of the injection device and manufacturing process.

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Potential risk	Contributing risk factors	Potential risk mitigations
Increase of extrusion force or injection time over shelf life due to silicone-oil migration	<ul style="list-style-type: none"> • Siliconisation/lubrication process • Silicone oil or lubricant level, distribution and stability over time • Protein concentration • Surfactant type/concentration • Age of PFS prior to filling • Storage temperature and time 	<ul style="list-style-type: none"> • Stability/compatibility study including functionality testing with worst-case (lowest and highest) lubricant/silicone levels
Needle clogging due to water vapour permeation through rigid needle shield	<ul style="list-style-type: none"> • Protein concentration • Water vapour transmission rate of the rigid needle shield • Stoppering process • Environment (humidity/climate zone) 	<ul style="list-style-type: none"> • Selection of a rigid needle shield (material) with a low water vapour transmission rate • Needle-clogging study (issue not uniform over batch)
Tungsten-induced protein aggregation	<ul style="list-style-type: none"> • Type of protein • Formulation (e.g. pH) • Protein-to-tungsten ratio • Stoppering process • Cone diameter • Washing process 	<ul style="list-style-type: none"> • Adequate formulation development • Tungsten spiking study (tungsten residues are not uniformly distributed within a batch) • Low-tungsten PFSs • Ceramic pins
Silicone-oil-induced protein aggregation	<ul style="list-style-type: none"> • Type of protein • Siliconisation process • Silicone oil level • Formulation parameter (e.g. surfactant type/concentration) • Transportation stress (interfacial stresses) 	<ul style="list-style-type: none"> • Adequate formulation development • Stability study in PFS with worst-case (highest) silicone oil level • Transport simulation study • Silicone-oil-free PFSs
Leachables	<ul style="list-style-type: none"> • Container and closure materials of contact • Label ink and glue (polymer containers) 	<ul style="list-style-type: none"> • Extractables and leachables studies • Assess primary packaging components for dry natural rubber/latex allergens • Stability studies in actual primary packaging
Loss of sterility due to stopper movement during air transport	<ul style="list-style-type: none"> • Stopper position (bubble size) • Altitude, mode and conditions of transport • Headspace pressure (positive or negative) • Container closure system material (plastic versus glass) • Silicone oil content and distribution • Temperature • Dimensions of container closure system components (and related variability) • Sterile barrier height of stopper 	<ul style="list-style-type: none"> • Adequate fill-finish process development (e.g. stopper setting) • Characterisation of stopper movement • Definition and control of stopper position • Study impact of transportation

Table 1: Examples of potential risks during drug-device integration, contributing risk factors and potential mitigations.

MANUFACTURING PROCESS DEVELOPMENT

SC formulations are often high-concentration protein formulations, which have a higher viscosity than water or placebo. Highly viscous formulations can impact the drug product manufacturing process. There are a number of aspects that are especially important to consider for manufacturing process development when working with high-concentration formulations for PFSs and cartridges for autoinjectors, pen injectors or OBIs.

Filtration Process

For aseptic manufacturing, formulations must be filtered to achieve sterility. Hence, the ability to be filtered is a key criterion when selecting a formulation. In addition, due to the high costs of the API, especially in high-concentration protein formulations, it is important to minimise losses during filtration. These are driven by:

1. The flush volume at the beginning of the filtration process
2. The filter hold-up volume.

The flush volume is required to account

for binding or adsorption of the API or surfactant to the filter, as well as to the residual water in the filter after the pre-use filter integrity test. Both can result in “underdosing” of the first-filled containers. Filter binding or adsorption for a given formulation is highly dependent on the filter membrane material and type. Therefore, to minimise the losses related to filter binding and adsorption, the filter membrane material should be selected carefully. Also, as filter binding and adsorption is formulation specific, the flush volume needs to be determined, unless it can be defined based on prior knowledge.

To minimise the losses related to the hold-up volume, the filter size or effective filtration area should be as small as possible while ensuring a high enough filtration flux and avoiding filter fouling.

Filling Process

Existing filling technologies have their own advantages and disadvantages, such as their accuracy and precision and their potential to induce protein particle formation. As such, selecting a filling technology that is suitable for a given formulation is critical. The filling parameters, including pump speed and tubing diameters, need to be optimised.

The pump speed needs to be synchronised with the motion of the filling needle to avoid dripping, clogging, splashing and foaming, as well as to ensure filling accuracy and precision. Filling needle clogging can occur during filling interruptions, especially when dealing with high-concentration protein formulations. Non-optimised filling parameters can lead to losses and a high reject rate during visual inspection due to a high fill-weight variability or filling needle clogging, which can potentially lead to abortion of the filling process and the need to discard the remaining bulk solution.

Stoppering Process

Stoppering of PFSs and cartridges can be done either by vent tube or vacuum stoppering. Each of the stoppering technologies has its own advantages and disadvantages. Vent tube stoppering generally has a higher throughput than vacuum stoppering, however, some coated stoppers can exhibit wrinkles in the coating after vent tube stoppering due to the compression in the vent tube and later relaxation. As these wrinkles can have an adverse impact on container closure integrity, the potential formation of wrinkles needs to be carefully assessed.

For some SC injection devices, bubble-free filling is required, which can be achieved with adequate knowledge and expertise, such as by using specific vacuum stoppering processes. The selection of the stoppering process also depends on the material properties of the plunger stopper. For example, some plunger stoppers cannot withstand the compression in a vent tube and need to be stoppered by vacuum stoppering.

The stopper position in the container will be based on the fill volume and its tolerances, as well as the process

capabilities. Furthermore, it is important to consider the impact of the stopper position on the assembly process and potential stopper movement during transportation, especially by air, where stoppers may move into non-sterile areas.

BRIDGING STUDIES

The extent and scope of a bridging programme is determined by the timing of change – development versus commercial – and the extent of the change between formats. Transitioning from a vial for IV infusion to an injection device for SC injection is the most complex scenario, and typically requires the most extensive bridging studies. Switching from an IV vial to an SC injection device post-launch has the advantage that efficacy, safety and required dose have already been established, and clinical studies may require fewer patients and time if regulators accept a non-inferiority PK study design.

Technical Bridging Studies

Transitioning from an IV vial to an SC injection device usually involves a change of the formulation to one with a higher API concentration to account for the lower bioavailability and limited volume of SC delivery. In some cases, it also involves a change from a lyophilised formulation to a typically less stable high-concentration liquid formulation. To manage stability and viscosity challenges, new excipients might be needed for the SC formulation. Therefore, a technical study is required, which typically includes a comparative stability study comparing pre- and post-change drug product formulations and presentations, for example, a vial and a PFS.

Given the change of the formulation and potentially the dosage form, the post-change drug product is typically expected to be less stable, given the higher concentration of API usually involved. In any case, it is important to assess the overall exposure of any degradant – considering the anticipated dose against the concentration of the degradant – and to assess whether any new degradants are present in the post-change formulation, which may require new toxicological assessments.

Preclinical Bridging Studies

Prior to introducing the SC formulation into clinical studies, at a minimum, local tolerance must be established in a good laboratory practice toxicology

study, as per Organisation for Economic Co-operation and Development (OECD) requirements. Additionally, PK and bioavailability may need to be estimated in a suitable animal model.

Clinical Bridging Studies

Prior to introducing the SC formulation into clinical trials, the new formulation at the higher API concentration is typically tested in human PK and bioequivalence studies. Based on the outcome, the dose, injection volume and dosing frequency are defined for later clinical studies.

It should be noted that the SC formulation for the preclinical and clinical bridging studies can theoretically be supplied in a vial presentation and does not have to be supplied in the commercial SC injection device, assuming that the stability of the SC formulation in the vial is comparable to the stability in a syringe or cartridge configuration. Although not generally recommended, Phase III trials can be initiated with an SC vial presentation with an introduction of the SC injection device later, such as in an open-label extension. It is recommended that such study designs are carefully discussed and kept in alignment with the respective regulatory authority.

WHY CHOOSE TEN23 HEALTH?

A CDMO such as ten23 health is appropriately positioned to support its customers with technical and regulatory experience when transitioning from a vial presentation to an injection device during clinical development, as well as post-launch. ten23 health's team of experts can design an adequate strategy from early stage to commercialisation to de-risk the development approach. ten23 health offers end-to-end services for sterile drug products, including IV and SC formulation development, drug-device selection, integration and testing, manufacturing process development, comparability studies, analytical development, clinical and commercial GMP fill-finish and quality control release and stability testing.

ten23 health provides its GMP fill-finish of complex and high-precision containers at its facility in Visp (Switzerland), including syringes, vials and cartridges, including the capacity to handle both glass and polymer containers on the same line. Therefore, when changing from a vial to syringe or cartridge configuration, no

transfers to other lines or facilities are required, making such changes – embedded into their respective technical evaluations – seamless.

ABOUT THE COMPANY

As a CDMO, ten23 health is appropriately positioned to anticipate and mitigate the technical challenges when developing formulation and manufacturing processes for injection devices. ten23 health offers integrated development of formulation

services, analytical development and product characterisation, device selection and testing, and drug product process design and characterisation. ten23 health also provides fill-finish manufacturing of complex and high-precision containers at its GMP fill-finish facility.

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ABOUT THE AUTHORS



Michael Adler, PhD, is currently Director Drug Product Design at ten23 health in Basel (Switzerland). He has over 20 years of industry experience at different pharmaceutical companies, including Abbott (now AbbVie), Roche, Lonza and ten23 health. He has vast experience in early- and late-stage formulation and drug product manufacturing process development for both liquid and lyophilised dosage forms. His area of expertise also covers process transfer, process characterisation and validation and commercial support for biological drug products, including combination products and small-molecule parenterals. Dr Adler has driven development of monoclonal antibodies and novel antibody-derived formats, fusion proteins, PEGylated proteins, synthetic peptides and oligonucleotides for IV, SC, intravitreal and intrathecal delivery. He has extensive knowledge with regards to regulatory registration activities, as well as health authority interactions for the US, Europe and elsewhere. Dr Adler studied Pharmacy at the University of Heidelberg (Germany) and holds a PhD in Pharmaceutical Technology from the University of Erlangen-Nürnberg (Germany).



Venkata Appa Reddy Goli is a Research Fellow, Formulation and Process Development, at ten23 health. He worked previously as a senior scientist at Thermo Fisher Scientific from 2021 to 2023, Biocon Biologics from 2019 to 2021 and Pfizer’s biologics development centre from 2014 to 2019. He has a pharmaceutical background and holds a master’s degree in Pharmaceutics from NIPER, Mohali (India). He has extensive knowledge of formulation development, container closure selection, lyophilisation and process development and characterisation. Throughout his career, Mr Goli has played a key role in platform formulation and process development.



Andrea Allmendinger, PhD, has been Chief Scientific Officer at ten23 health since November 2021. Dr Allmendinger is also Adjunct Professor and Group Leader at the University of Freiburg (Baden-Württemberg, Germany), researching novel parenteral drug formulations and device solutions to improve stability, usability and cost of goods. Between 2010 and 2021, she was Principal Scientist, Pharmaceutical Development at Roche, working on inter alia manufacturability and injectability of high-concentration formulations, syringe and high-volume drug/device combination products, particulates and surfactant strategy. Dr Allmendinger studied Pharmacy at the University of Heidelberg (Germany) and University College London (UK), and holds a PhD in Pharmaceutical Sciences from the University of Basel, Switzerland. She obtained the *venia legendi* (German Habilitation) from the University of Freiburg in 2021, and serves as Editor-In-Chief for the AAPS Open Journal.



Professor Hanns-Christian Mahler, PhD, is Chief Enablement Officer and Board Member at ten23 health. He previously led the Drug Product Services Business Unit at Lonza AG (Basel, Switzerland) (2015–2021) and worked in various leadership roles, such as Head of Pharmaceutical Development & Supplies at Roche (2005–2015) and Merck KGaA (2000–2005). He has extensive expertise in formulation development, process development and validation, packaging/device development and integration, sterile manufacturing and regulatory submissions with numerous IND/IMPd and BLAs. Professor Mahler studied pharmacy at the University of Mainz, Germany, and holds a PhD in toxicology from the Institute of Pharmacy, University of Mainz, and pharmacist specialisation degrees in toxicology and ecology, and pharmaceutical technology. He also has qualifications in Business and Marketing (AKAD University, Germany). Professor Mahler obtained his *venia legendi* from the University of Frankfurt, Germany, in 2010 and is adjunct faculty member and lecturer at the universities of Frankfurt and Basel. He also serves as Editor for *Pharmaceutical Research*, *Journal of Pharmaceutical Sciences*, *AAPS Open Journal* and *PDA Journal of Pharmaceutical Sciences and Technology*.

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