WHITE PAPER

AUTOINJECTORS
FROM PLANNING TO LAUNCH

Preparing for the overall development process
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1 INTRODUCTION

1.1 OVERVIEW

Looking at the rising trend towards self-administration therapies, injectable drug delivery devices such as pen injectors, autoinjectors and needle-free injectors show a significant growth potential in the near future.

In 2010, the pen systems and autoinjectors market was estimated to be worth over $0.58bn, a growth of 8-10% from previous years. It is estimated that the market will continue to grow steadily between 10-15% over the forecast period. It will reach $0.87bn in 2013 and $1.07bn in 2015. (Visiogain, June, 2011)

Driven by the corresponding industry demands, biopharmaceutical companies have since introduced a large range of solutions for delivery of injectable drugs and continue to push for improvements in every aspect. In fact, industry analysts have estimated that over 30% of all new product submissions to the FDA are combination products with autoinjectors being one of the fastest emerging solutions.

While the autoinjector is now often considered by many biopharmaceutical companies to be a suitable device to commercially launch their therapeutic drugs in, to do so successfully requires detailed planning, combination product knowledge, regulatory awareness and even more importantly, close collaboration with a carefully chosen device manufacturer. Unfortunately, biopharmaceutical and device companies have different product lifecycles and development processes which can lead to process gaps that are crucial to the overall project and can ultimately influence the product’s speed to market. It is therefore imperative that the biopharmaceutical company has a thorough understanding of all related processes, when and where to involve the device manufacturer, how to meet the corresponding regulatory demands for combination products, what core competencies to seek and more.

This white paper focuses on assisting biopharmaceutical companies in taking a closer look at the development process of the secondary packaging of an autoinjector project from planning to launch and best practices on how to prepare for and address potential challenges along the way.

1.2 A COMBINATION PRODUCT IS A JOINT EFFORT

An autoinjector consists of a pre-filled syringe (PFS) or cartridge and a mechanical mechanism inside a device to deliver the drug.

Combination products require close collaboration between biopharmaceutical companies and device manufacturers who have different product life cycles.

For patients, some beneficial features of the autoinjector include reduced dosage errors, integrated needle safety and a mechanical design that can overcome patient concerns such as needle phobia and dexterity challenges. As a healthcare provider, aside from simpler and more streamlined preparations, the autoinjector also offers a safer alternative that can help prevent against needle stick injuries, a major concern that on average causes between 600,000 to 1 million injuries in the US (US Medical Instruments, Inc., 2006) and a global injury rate affecting up to 3.5 million individuals (Prüss-Ustün, Rapiti, & Hutin, 2005). The severity of the injuries...
widely used in recent years and many biopharmaceutical companies are familiar with the associated stability and compatibility concerns such as extractable and leachable implications on the contained biologics. However, with researching and developing drug formulations the traditional focus for biopharmaceutical companies, integrating the PFS into an autoinjector brings new challenges in areas of unfamiliar expertise such as mechanical design and manufacturing and will involve immense education and awareness as well as a carefully chosen partnership. New items that will require such attention may range from the initial user-centric design of the device to the assembly of the components, associated regulatory matters and more. Assuming the biopharmaceutical company has specified the type of PFS (e.g. standard 1mL long) to use in the autoinjector and an associated primary packaging vendor, considerations of the above secondary packaging matters and choosing a device partner becomes another key piece for the success for a combination product.

With so many interrelated variables, a biopharmaceutical company that wishes to venture into the autoinjector market will need to understand what core competencies to seek for in a device partner and educate themselves with the overall autoinjector development process and pitfalls to avoid as early as the planning stage. Once a chosen device manufacturer is engaged,
close and frequent communication will be essential during all phases from planning to launch to ensure potential bottlenecks are either avoided or addressed in a timely fashion. The extent of the joint effort between the biopharmaceutical and device companies can determine the overall success of the autoinjector project.

1.3 FROM PLANNING TO LAUNCH

Introducing a competitive product that meets user needs and can be launched within the desired time to market is the ideal goal for any biopharmaceutical company. Working towards this goal becomes a reality as the biopharmaceutical and device companies come together to design and coordinate an autoinjector project.

The chart is broken down into three main stages: Planning, Development and Launch, and will be discussed in more detail in the subsequent sections of this paper. However, as with any product that involves end-user experience, linearity is almost never an option as post-launch product responses should circulate back to directly influence future development of similar projects and be factored into future design considerations (see Figure 4). Understanding and applying this concept is part of a series of best practices that will also be discussed later in this paper and can add value to similar autoinjector projects the biopharmaceutical company takes on in the future. After all,

“A product that stops being better stops being good”
2 PLANNING

2.1 GENERAL SCOPE

With a majority of biologics recently introduced or in development made from complex chemical compounds, traditional oral intake methods may no longer be an option as the digestive system can cause unwanted chemical reactions. Looking to other alternatives, delivery methods ranging from traditional vials, PFS, safety syringes and autoinjector may all be considered. For biopharmaceutical companies that plan on introducing an injectable drug with special properties (such as high viscosity) and/or delivery methods (such as self-administration), the autoinjector may quickly become prevalent in the pool of preferences.

A biopharmaceutical company should initiate discussions both internally and with a potential device partner regarding what potential final delivery platforms to use as early as Phase I of a drug’s clinical trials. With delivery specifications such as dose ranging likely studied at this stage, involving a device manufacturer early can help identify possible mechanical limitations for delivery specifications and allow more time for the device manufacturer to innovate around them. For example, highly viscous drugs will require specially designed mechanical mechanism for delivery but the corresponding shear force may have unprecedented effects at a chemical level. Discussing such issues early can impact the development timeline to follow. At this point, the question of how well prepared the company is should also come to mind, including the range of internal resources accessible and traits to seek in the chosen device partner. This initial evaluation is crucial especially if one has little or no experience with combination products. A prepared team will be the first essential step towards the right direction.

2.2 INTERNAL RESOURCES

The team assembled for leading an autoinjector project should first evaluate if the following items are available internally:

2.2.1 Cross-functional Expertise

Sufficient cross-functional expertise ranging from empirical to regulatory and basic mechanical device knowledge is essential on the team in order to better prepare for the project:

**BASIC MECHANICAL DEVICE KNOWLEDGE**

A biopharmaceutical company may have abundant experience working with therapeutic drugs and even introducing them into a PFS, but may have none in integrating them into an autoinjector. While finding a partner with the right expertise in this area is crucial, obtaining some basic mechanical device knowledge can help the team better prepare for the device-drug combination product. Various autoinjectors already exist on the market and with some thorough research, the assembled project team can discover what aspects of the device’s mechanical design should be attended to most and specified to accomplish the administration for the desired drug. Such standard specifications may include:

<table>
<thead>
<tr>
<th>Specification</th>
<th>Example(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delivered Dose</td>
<td>1.0mL</td>
</tr>
<tr>
<td>Viscosity Range</td>
<td>1-50cp depending on needle and injection time</td>
</tr>
<tr>
<td>Injection Time</td>
<td>Over period span of Seconds</td>
</tr>
<tr>
<td>Injector Mechanism</td>
<td>Mechanical, Electronic</td>
</tr>
<tr>
<td>Injection Depth</td>
<td>Intramuscular, Subcutaneous</td>
</tr>
<tr>
<td>Primary Container</td>
<td>Prefilled Syringe (PFS), Standard or Dual Chamber Cartridge</td>
</tr>
<tr>
<td>Activation Method</td>
<td>Button Activated, Shield Activated</td>
</tr>
<tr>
<td>Feedback Mechanism</td>
<td>Audible, Visual, Tactile</td>
</tr>
<tr>
<td>Needle Protection</td>
<td>Rigid/Rubber Needle Shield, Passive Needle Cover</td>
</tr>
<tr>
<td>Usage</td>
<td>Single Dose, Multiple Dose</td>
</tr>
<tr>
<td>Dosage Type</td>
<td>Fixed, Variable</td>
</tr>
<tr>
<td>Needle Attachment</td>
<td>Pre-attached, Manually Attached</td>
</tr>
<tr>
<td>Needle Insertion/Removal</td>
<td>Automatic, Manual</td>
</tr>
</tbody>
</table>

![Figure 5: Planning Checkpoints](image)
The above is only some of many possible specifications that will affect the mechanical design of the autoinjector. More details and guidance will often be provided by the device company who may design the autoinjector to fit a range of injection specifications. Having a fundamental understanding of the device’s mechanics beforehand allows for a more accurate and detailed initial requirement request to the device company later on. Clearly specifying the mechanical needs for the drug at the initial stage can also minimize time consuming adjustments later and enhance communication, pushing the project forward more quickly and efficiently.

However, unless members of the team have had extensive experience with mechanical devices, there will still be a limit to the amount of knowledge that can be obtained during planning whether it’s through studying or utilizing other consultative means. Taking apart an autoinjector to analyze its mechanical makeup is possible and can prove to be useful, but comprehending fully the design intentions behind each component is altogether more difficult without an intimate knowledge of the device design history and is better left for the device manufacturer to provide.

Other mechanical features of the autoinjector such as safety features and activation method will also have a direct impact on end user experience, making it even more imperative to acknowledge and factor them in at an early stage.

**REGULATORY EXPERIENCE**

As the drug and device companies come together to work on an autoinjector, they will enter an unfamiliar territory where the combination of the pharmaceutical cGMP (current Good Manufacturing Practice) regulation and device Quality Systems Registrars (QSR) must be applied for the US market, requiring close communication between both parties. At least one member of the biopharmaceutical project team should be aware of all related regulations and establish a communication protocol with the device company early, so as to ensure submissions do not delay project timelines. Likewise, the partnered device company should have a team of regulatory experts with experience working with the FDA on combination product submissions as part of its core services.

While the purpose of the cGMP regulation and QSR are to ensure that quality standards and regulatory requirements are met, they are tailored for very different products, making it challenging to grasp at times. Fortunately, the FDA recently published draft guidance on drug/device combination products, a document that should be familiarized by the regulatory team on both sides during the partnership.

This guidance and further information can be found at the FDA website (http://www.fda.gov/CombinationProducts). For the EU market, a solid understanding and implementation of the Medical Devices Directive (93/42/EEC) is crucial. Depending on the type of autoinjector (i.e. disposable or reusable) the device may require a CE mark. Directly speaking to and seeking advice from the corresponding regulation agencies and describing the type of combination product to be developed can also prove to be helpful.

Regulatory planning is critical to an autoinjector, as submission deadlines can drive project timelines; thus, sufficient planning, preparation and awareness is critical. Combination products such as the autoinjector can sometimes involve more than one type of regulatory submission in order to market and distribute the final product. (i.e. for the drug and separately for the device). It thus becomes even more valuable to have cross-functional expertise on the project team, including members who have experience working with drug/device combination products (such as inhalers) or with similar drug delivery products such as PFS and safety syringes. Familiarity with relevant manufacturing processes may prove to be helpful, but a biopharmaceutical company that focuses on excelling in drug research may find it more practical to source out a manufacturing device partner who has the technical expertise and familiarity with FDA recognized standards required for testing of drug/device combination products.

Whether the final product is for the US and/or the EU markets, cooperation between the biopharmaceutical and device companies is critical for the required pre-approval inspections by regulatory authorities. A joint effort must be made as to who will be responsible for the various compliance documents and where they will be stored.

2.3 IDENTIFY A KNOWLEDGEABLE AND EXPERIENCED PARTNER

With a prepared internal team now ready, the biopharmaceutical company can begin evaluating different device manufacturers as their potential secondary packaging partner.

2.3.1 What to look for in a Device Partner

In-house manufacturing capabilities, regulatory experiences, structured risk and management processes are just some of the vital traits an ideal device manufacturer partner should have to ensure the end product quality, regulatory compatibility and time to market.
While many device companies in the drug delivery industry have experience working with autoinjector projects, only a few can provide the range of core competencies needed to successfully see the project through from planning to launch. The list below is a proposed guidance for the biopharmaceutical company to reference when seeking a partner.

- Possessing key core capabilities in-house allows the device company to have full control and ensure quality as well as addressing changes in a timely manner.
- Regulatory team from the device company should be experienced with similar projects and familiar with related submissions.

IN-HOUSE MANUFACTURING CAPABILITIES

In-house manufacturing capabilities are vital when supporting design changes during scale up or any other development stages. Some core capabilities to seek for in a device partner include:

- Tooling
- Molding
- Assembly
- Automation
- Metrology
- CNC Machining

Manufacturing an autoinjector requires complex processes and machinery. By possessing these capabilities in-house, the device company will have full control of the development processes under one roof, ensuring quality and addressing any needed design changes in a timely manner while the autoinjector is still being optimized to meet usage requirements. As an example, dimension precision of components is key to ensuring the autoinjector’s proper assembly. With molding and tooling held in-house, new injection molds can quickly be provided to support the often frequent adjustments to the components dimension.

Offering an extensive range of core manufacturing capabilities indicates that the manufacturer has made significant investments to provide a business model that makes most sense for the biopharmaceutical company, a trait signifying the dedication to the project. Overall, a device company that can provide the latter will have better insight of the autoinjector’s development stages, anticipated product lifecycle and a solid knowledge base that can help better determine and manage project scopes.

REGULATORY AWARENESS

As important as being familiar with regulations such as the cGMP regulations, QSR and MDD, the device partner needs to have strong awareness of how associated regulations may affect the overall timeline. Ideally, the available regulatory team from the device company should have experience with similar projects and related submissions, so as to provide insight and specialized considerations when working with the biopharmaceutical company on projecting timelines. Regulatory teams from both the device and biopharmaceutical companies will also need to communicate early and frequently to define the intended use, indication for use and targeted markets of the combination product as well as the corresponding regulatory pathway required to achieve final approval. Necessary documentation should also be available to meet biopharmaceutical company’s corresponding clinical trials and associated submission dates.

Working with a partner that already has 510(k) clearance on device platforms can also significantly expedite the overall submission process and is a desirable trait the biopharmaceutical company should seek in a device partner.
2.4 LONG-TERM IMPROVEMENT MEASURES

2.4.1 Systematic Documentation

An autoinjector project can take on average anywhere from 2 to 5 years to complete. With this time span, it becomes essential to establish a systematic documentation process internally beyond Document History File (DHF) regulations. This process should build towards a comprehensive knowledge bank in areas such as choice of material, justifications for device design adjustments, handling study parameters, regulatory obstacles encountered, post-market feedback and more. The centralized knowledge bank can provide reference for the rationale behind each key project decision and reduce miscommunication amongst the many team members that may get involved during a potentially long project time span. For similar projects in the future, new project members can save significant time by referring to these documents to better understand the overall scope of an autoinjector project and to avoid any known issues documented early.

The implementation of such a system is subject to how each assembled team operates but should be ready as early as planning stages.

2.4.2 Post-market Performance Monitoring Measures

The autoinjector, compared to the traditional drug administered in a hospital or clinic setting, is mainly distributed through retail pharmacy portals. This adds a layer of complexity as users are directly purchasing a mechanical device and if not properly trained, can encounter struggles due to incorrect usage. Consequently, the product’s market performance can quickly be affected if a thorough customer training and service program is not in place to support the post-launch.

Developing such a program requires involving the biopharmaceutical company’s internal Sales/Marketing and Regulatory teams, sharing with them vital handling study results and device usage instructions to allow a decent understanding of the device from the user’s perspective. This program should also include complaint handling procedures to address and collect reported issues. Whether the cause is due to human or mechanical factors, the system should ensure the reports are circulated back to both the biopharmaceutical company and device manufacturer for further review and troubleshooting.

Another criterion to consider for the commercial market when choosing a device partner is the company’s actual market scope. In other words, whether or not they have experience in developing a globally launched device can determine if adequate experience will be embodied within their development and manufacturing processes.
3 DEVELOPMENT

The administration requirements of every drug are unique depending on its therapeutic purposes and affects how the autoinjector device should be designed. As these requirements are translated into device specifications, the decision to customize an existing platform or to develop a new device is one that the biopharmaceutical company needs to make before proceeding to development stages. With the device knowledge and experience residing mostly with the device manufacturer, an ideal partner should be capable of providing assistance in assessing which development route corresponds to the biopharmaceutical company’s business model the most.

Finding the balance between cost, time and the device will be one of the major determining factors when finalizing on a suitable route. Choosing an existing platform allows for further device customization, and can imply cutting additional cost and time associated with pre-study and prototype phases. A traditional development program on the other hand indicates a longer development cycle but results in a brand new device which may better meet market demands.

Whichever route the biopharmaceutical company decides to take to initiate the autoinjector project, accurately defining a set of design input requirements (DIRs), a document that specifies the detailed requirements and purpose of the desired device, is a vital step to kick-start the development process. Such definition should encompass key functional prerequisites that can fulfill patient needs and indicate the range of corresponding device design required. This may include cartridge specifications, drug type, injection route, injection time, intended use, regulatory and functional requirements, risk management plan, etc. Accurately identifying these properties is only possible if the pharmaceutical company is well prepared for projects of this nature.

Finally, during the development phase, clear and constant communication is essential to a successful collaboration. In addition, a competent partner with the core capabilities to provide timely enhancements will help make the development process run more smoothly.

3.1 DESIGN COMMUNICATION

The DIRs in document form will serve as a communication tool between the biopharmaceutical and device companies and be used to identify needed adjustments for the preliminary device prototype. The DIR is a living document that will also be leveraged to define critical process steps and testing parameters, ultimately affecting the setup of the subsequent manufacturing processes and related key quality attributes.

At this stage, gaps between expectations based on empirical parameters and actual mechanical executions will quickly emerge, making it imperative for the drug and device companies to hold regular meetings to discuss possible solutions. The project management teams should now act as the window of contact and coordinate this communication, holding regular sessions to ensure both parties are fully informed of any needed changes. Design control regulations will also need to be applied to clearly define the design activities and changes taking places as well as when formal design reviews need to take place.
3.3 Tooling and Molding

As it requires a significant investment to establish an in-house tooling center, some device manufacturers prefer to out-source their tooling to 3rd party vendors. At first glance, it may make more economical sense to do so, but this can quickly become a bottleneck during development for various reasons.

Additional time will accrue as another layer of communication is now required for every adjustment and can easily delay the project timeline. The matter of quality supervision also becomes difficult as the processes are now taking place at a different site with a different team. With the autoinjector being a relatively new product, it becomes difficult to find a tooling vendor that has experience in the area of autoinjector molding. Subsequently, even more time will be required to educate and oversee the processes, with the likelihood of increased error due to lack of experience.

By working with a partner in-house tooling and molding centers and knowledgeable engineers and operators, the above issues can be significantly minimized, providing a more streamlined and time effective solution for the biopharmaceutical company. Equally important is securing the associated intellectual properties within one partner as opposed to sharing with various 3rd party vendors.
3.4 AUTOMATION

With the requirements of the biopharmaceutical company and the targeted user groups differing largely for every project, there are endless possibilities in the final device produced. Every product will be customized in terms of how they are tested and assembled and will be impacted by the automation capabilities available.

During the initial design phase, the device company’s testing department needs to ensure the items specified in the DIR can be properly carried out and tested for verification. Unfortunately, to do so also requires a large range of custom-made fixtures, testing and assembly machines. By working with a device manufacturer that has automation in-house, drug companies can avoid the additional time needed to communicate with an external machine vendor every time a new test needs to be performed and focus on ensuring the DIR requirements are met accordingly.

As the volumes of device to be tested and assembled increases, how processes are set up can also quickly impact the progress of each development phase.

3.5 FINAL ASSEMBLY

Depending on the biopharmaceutical company’s business model for the autoinjector project, the choice of how the final device sub-assemblies are assembled may vary ranging from assembling themselves to outsourcing it to a filling company or a packaging company.

Assembling an autoinjector requires customized equipment which may have long lead times. Consequently, having a partner that has the capability to provide assembly services in-house can address such impending support at the right point in time. As the choice of the autoinjectors shape, material and other design aspects change, so will the design of the required assembly machine. This is where having automation capabilities and expertise in-house is ideal as customized assembly machines can be made for the biopharmaceutical company to utilize.

3.6 QUALITY CONTROL

Once the autoinjector design has been verified, validated and adjusted to accommodate scale up parameters, the device is ready to enter mass production where strict quality control becomes essential. At this point the biopharmaceutical company will have to depend heavily on the manufacturing partner’s facilities, experience and competency as the finalized device design is transferred to and implemented in the production environment. However, the biopharmaceutical company should be aware of the established manufacturing processes and quality standards being executed. Some of the methods employed may include statistical process control, product release inspection and functional tests to prove product conformity, which are applied to finished products or purchased materials. The quality controls of the manufacturing processes and various equipment used, as well as environmental and facility factors, must also be monitored, maintained and controlled.

Well documented procedures and inspection results should be readily available and be part of the final product release.
4 LAUNCH

The biopharmaceutical company will be responsible for the details of the autoinjector’s commercial launch. However, the partnership with the device company does not end here.

4.1 POST-PRODUCT LAUNCH

As all biopharmaceutical companies are already aware of, a project does not end at launch. It is in the nature of a commercial product that tremendous amounts of support will be required to handle post-launch issues such as the previously mentioned customer services and complaint handling programs. Ideally, the design of the autoinjector at launch has already addressed the vast majority of potential issues through a carefully designed and tested DIR and various handling studies during development. Quality control measures should have also helped assure standards.

Nonetheless, user responses are unpredictable and usage or device concerns can still surface especially with high volumes in the millions or when introducing to a brand new market segment. To address this, the biopharmaceutical company team responsible for post-launch support should be trained to diagnose and differentiate between issue types and only escalating potentially mechanically oriented cases to the device manufacturer for further review. It is important to note that by the time the user receives the autoinjector, numerous variables aside from the device’s mechanical design have been added which could have caused usage problems. For example, the final product may have been stored or shipped in inappropriate environments, causing chemical changes in the biologics inside the autoinjector. Insufficient user training or unclear instructions for use can also be a contributing factor to user complaints. Finally, a small percentage of possible mechanical related issues should be expected especially when larger volumes of devices are produced.

**Figure 10: Launch and Post-Launch checkpoints**

Properly sorting reported issues and sharing added variables can help the device manufacturer focus on replicating scenarios, addressing and justifying potential design related device causes. The final root causes are to be well documented in a knowledge inventory for both the device and biopharmaceutical company to refer to in the future. In addition, aside from communicating potential issues of a mechanical nature, feedback from other perspectives such as the biopharmaceutical’s marketing team can help the device manufacturer better understand user preferences.
5 CONCLUSION

When designing a combination product such as the autoinjector, insufficient planning and early conceptual design vulnerabilities can easily result in quality issues, prolonged project timeline and increased cost. It is imperative for the biopharmaceutical company to not only educate internal teams on the overall process flow of an autoinjector project early, but also to carefully choose a device manufacturing partner with an established track record, extensive regulatory experience and a wide range of in-house capabilities to support the ever-changing nature of the project.

During development, ensuring the design addresses critical quality attributes related to the device’s safety and efficacy is key and can be accomplished through close communication and vigilant DIR changes, where necessary, with the device partner. Understanding all associated regulations beforehand and scheduling so submissions deadlines do not become bottlenecks will also impact greatly on development speed and time to market. Finally, carefully analyzing and troubleshooting the device’s post-launch market responses and user feedback is vital as user responses can reflect missing components not defined in the original design requirement input and be considered as an additional parameter for second generation devices or similar projects in the future.

Mainstream use of the autoinjector combination product will continue to be a growing trend in the pharmaceutical market as the demand for biologics increases and biopharmaceutical companies need to protect market share with competitive products that offers improved efficacy, convenience and safety. Understanding the associated development processes from planning to launch, required preparations and potential challenges will be the first step towards project success.

6 REFERENCES


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