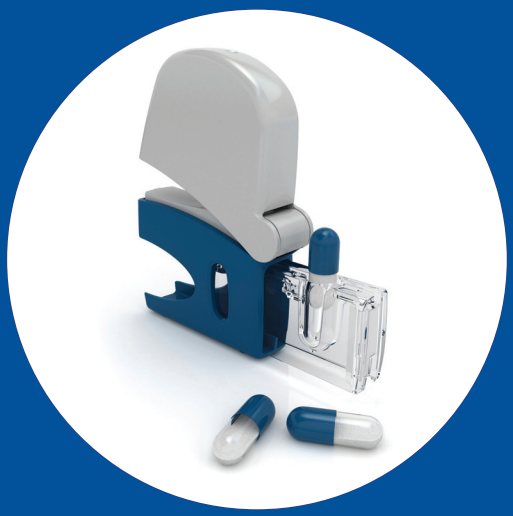
H&T PRESSPART



Innovation at H&T Presspart

Product and Process Innovation

LIVING AND BREATHING DRUG DELIVERY

Member of the HEITKAMP & THUMANN GROUP

INNOVATION AT H&T PRESSPART

This innovation magazine provides you with an overview of selected innovation topics and projects that are important to H&T Presspart.

"Most companies that don't innovate die," says Henry Chesbrough. Innovation is the driving force behind progress and sustainable organic growth. For H&T Presspart, innovation has always been at the center of its corporate philosophy and entrepreneurial activities. We put our trust in a culture of innovation that is employee driven. We build upon the strengths we have at all three H&T Presspart sites, and as being members of the Heitkamp & Thumann Group. We focus on validated learning and try to follow the famous innovation phrase: "fail fast and cheap to succeed sooner".

For H&T Presspart innovation is the process of making changes, large and small, radical and incremental, to products, technologies, processes, business models and services. These changes need to result in something new that adds value to our customers.

This magazine is dedicated to selected topics on product innovation and process innovation. We would like to thank Chad Mayoh and the various project teams for their great contributions to this newsletter.

We now wish you an insightful reading experience and look forward to discussing further H&T Presspart innovation topics with you in the future.

Best wishes,
Matthias Seiler, Julian Hemy, Victor Torres

Julian Hemy
H&T Presspart Co-Chairman
& Commercial Director

Victor Torres
H&T Presspart Co-Chairman
& Global Technical Director

CO-CHAIRMEN'S INTERVIEW

Mr. Hemy: Mr. Torres and you are the two new Co-Chairmen of H&T Presspart. Why do you think innovation is important to your division?

We say in our vision statement of the Heitkamp & Thumann Group 'Innovation will create our future'. At H&T Presspart, we take this very seriously. We strongly believe that driving product and process innovation and continuously strengthen our 'innovation culture' will be key to achieve our ambitious growth goals.

Product Innovation is crucial to ensure that we maintain and improve our market position by offering new system solutions to customers that solve their problems. Process Innovation is crucial to improve our costs offering benefits to customers whilst maintaining our profitability and ability to invest. And of course, innovation in general is crucial because it also energises the organisation and helps to further strengthen organizational learning and our global team coherence. At H&T Presspart every single colleague, from the shop floor up to the top, contributes to our innovation initiative and thereby helps to shape our future.

Mr. Torres, what have been the innovation success stories and challenges of the last year?

Pharma products and processes typically require significant space and infrastructures, both limited and very capital investment intensive due to the specific high standards required in this industry.

For some of our core products, market volumes are growing but becoming more and more fractioned, hence the number of stock keeping units with low volumes is growing exponentially. Standardization, achieving a high degree of flexibility with low operational costs, space optimization and making sure return on assets is within the H&T Group target is a complex, multidimensional and exciting challenge which requires good product and process engineering together with a strong team innovation thinking.

We are very excited with some innovative products being developed: prototypes are almost ready to run preliminary design validation tests and to check 'Voice of the Customer' later in 2018 which address these issues very well.

Also, great success stories can be physically seen at our three sites in Blackburn, Marsberg and Tarragona. We are redesigning their manufacturing areas for a more flexible and effective way of manufacturing products for the Pharma industry.

A big challenge we still focus on is to walk the talk in terms of following our guiding principle 'Fail fast and cheap in order to succeed sooner'. This is an area with a huge potential: On the one hand, it means rigor and discipline to say 'no' in an early phase to ideas and young projects that sound attractive but for which the strategic fit is not adequate. On the other hand, being stringent and sometimes cruel at the fuzzy front-end results in more available resources for executing our most promising innovation projects that succeeded in passing all gates of our customized stage-gate process. Our 'innovation culture' reflects this very well.

Mr. Hemy, what is your innovation vision for H&T Presspart?

We aim to distinguish ourselves from our competitors. Most of our competitors are large companies and groups that focus very much on product development and approach their markets from this angle. We do things a little differently. Our aim is to maintain our strong customer focus and we therefore try to work on innovative solutions together with our customers.

As a result, in many cases, we do not claim to develop our own products but wish to do so in cooperation with our partners. We originate from a traditional metal-forming background and have expanded to plastics through acquisitions. In the past few years, we have succeeded in combining our traditional business with our innovative products. We always look at innovation in the selected sectors in combination with the question, "How can we work together with our customers to provide future-oriented, innovative solutions with a clear and sustainable differentiator?"

Mr. Torres, how important is the topic Innovation Culture to you?

H&T innovation culture, with values and behaviors embedded in our company DNA, results in strategic idea generation which is strongly supported by the top management, because its importance is recognized as a differentiating factor for us to enhance our customer satisfaction. Identifying so-called hidden customer needs is key to generate ideas with a sustainable differentiator. To incorporate valid ideas to feed our "build-measure-learn" feedback loop for new product development using minimum viable products (MVP) allows us learning and making quick decisions with a minimum amount of effort.

With respect to strengthening our innovation culture, we saw huge progress during the last years. As Mr. Hemy said in the beginning, we strongly belief that driving product and process innovation and continuously strengthening our 'innovation culture' will be key to achieve our ambitious growth goals. Every executive and senior leader at H&T Presspart must be a role model to strengthen the innovation culture of H&T Presspart based on our 'golden seven key attributes'. Take a look at them in the table on page 28 of the magazine.

Only through the involvement of employees in this way are we going to be able to succeed in achieving positive, sustainable results in our efforts to really stand out on the market and make our company future-oriented.

Mr. Hemy, what are prominent H&T Presspart examples for product innovations and process innovations?

As you will be able to read in this brochure, there are a lot of fascinating stories. All cases where we contribute to solve challenges of our customers or even the end user. Product innovation wise I would like to mention our products PowdAir PLUS, Quantum, eMDI and also our counting solutions. All of them are described on the following pages. And of course I should not forget to mention our proprietary and industrialized Plasma process for the surface treatment of MDI cans.

Mr. Torres, you already mentioned the popular mantra "fail fast and cheap to succeed sooner" which is often very important for successful innovations in a B2B setting. Do the innovation activities at H&T Presspart involve a lot of learning from mistakes?

Driving innovation into the business mentality requires learning (also from failed projects) and change. Especially managing the balance between creativity and value capture requires learning systems. Otherwise, despite best intentions, one of the two aspects (creativity with long-term focus or value capture with short-term focus) always becomes dominant over the other, and the balance is lost leading to poor innovation results. Since assumptions about the unknown generally turn out to be wrong, product development projects inevitably experience deviations from their original planned targets.

We aim to systematically convert our joint project assumptions into knowledge as a strategic project unfolds and jointly identify and minimize a business plan's vulnerabilities. To make this happen, we need to use the right knowledge management tools and involve our most experienced managers with different backgrounds and sometimes also from different business units / divisions. We want to constantly learn with and from each other and leverage our core competencies also beyond department borders to identify additional ways of achieving strategic competitive advantages that can be sustained.

Managing our H&T Innovation Portfolio allows us Identifying, funding, supporting and also making tactical decisions to kill some innovation projects "fast and cheap" so we can focus on those opportunities which deserve the most resources.

Mr. Hemy, without giving away any confidential details, could you mention the important directions in innovation that H&T Presspart is taking? Could you also mention the competency or product areas in which your customers can expect new offers from H&T Presspart in the future?

At H&T Presspart, we have a relatively narrowly defined strategic grid. And that is because we do not want to move too far away from our core sector based on our technical as well as our market-relevant core competencies. In principle, we are focused on the pharmaceutical industry; more specifically on drug delivery systems especially in the field of inhalation. We are a world leader in the pMDI (pressurized metered dose inhalers) sector to treat asthma and COPD (chronic obstructive pulmonary disease) patients.

We are striving to become a one-stop shop for our customers. And this is not just because our customers find it easy and important to get a comprehensive range from one vendor but also because the components manufactured by us are technically dependent on each other to a great extent. It is therefore good to attempt to expand our portfolio systematically.

We want to grow in the field of inhalation in other sectors as well. We therefore work intensively on the development new innovations such new Dry Powder Inhalers (DPI). You can certainly expect some innovations in this area in the future. We are also moving into so-called adjacent market segments, which are closely related to our business. One such area is that of nebulization (dispensers), where we look to manufacture components and devices for drug delivery systems in the area of drugs for the nose, eyes, and ears and are working intensively towards expanding in these sectors.

Digital transformation in the healthcare sector, and particularly in the pharmaceutical industry, is another major core subject for us. The insulin sector is a pioneer for this in the pharmaceutical industry. The sector is already extensively focusing on digital innovations and this development is bound to penetrate into other sectors as well. We are obviously taking the inhalation sector as the basis for developing a value-adding digital transformation platform for our existing and potential customers.

Prof. Dr. Keith Goffin
Professor of Innovation and New Product Development, Stockholm School of Economics, Sweden

Emeritus Professor of Innovation, New Product Development and Process Management, Cranfield School of Management, U.K.

PRODUCT INNOVATION

H&T PRESSPART HAS A LONG HISTORY OF INNOVATION AND IS AIMING TO BOOST ITS OUTPUT OF NEW PRODUCTS. PROFESSOR DR. KEITH GOFFIN DISCUSSES THE CHALLENGES OF DEVELOPING NEW PRODUCTS THAT ADDRESS CUSTOMERS' HIDDEN NEEDS.

Many companies are focused on innovation and senior managers want their R&D departments to design something as novel as Apple's iPhone. However, most companies struggle to come up with novel ideas for new products. Every year, from the thousands of new products developed worldwide, product failure is more common than success in both the business to consumer (B2C) and business to business (B2B) sectors. What are the common reasons why products fail and what steps can companies take to prevent failure? This article will explain the key lessons from innovation research and how managers can apply them.

CAUSES OF PRODUCT FAILURE

The first lesson from research is that failure rates are high — many products fail to reach sales goals. Sometimes products fail because customers find they do not function correctly but by far the greatest cause of failure is a lack of product differentiation.

Products must be differentiated —they must clearly stand out from the competition. Truly differentiated products offer unique features that provide real customer benefits. Research has shown that such products have an 80% chance of success, whereas me-too products (which simply replicate competitors' features) have only a 20% chance.

Breakthrough products (or so-called semi-radical innovations) stand out from the competition because they are based on a deep understanding of customers' needs.

MAKING MARKET RESEARCH WORK

The B2C sector has a long history of conducting market research and many companies are known for conducting surveys and focus groups. But few B2B companies are proficient with such market research methods. In addition, focus groups and surveys rely on asking customers direct questions about the features they would like in future products. Direct questions are simply not effective since many B2B customers struggle to articulate their needs, or simply ask for further improvements to existing features. So conventional market research leads companies to develop incremental, me-too products and of course these have little chance of success.

To avoid what is called the incremental product trap, leading companies like H&T Presspart are using sophisticated techniques to uncover customers' hidden needs—those needs that customers are unable to articulate or have not even recognized themselves.

Such techniques are based on the social sciences (such as sociology, anthropology, and psychology), which focus on developing a deeper understanding than what can be achieved through direct questioning.

Hidden needs analysis is the name given to a collection of tools and techniques from the social sciences that can be applied in market research. The main techniques are repertory grid analysis (from psychology), ethnographic market research (from anthropology), and lead user groups. Each of the techniques has significant advantages compared to traditional market research and, when used in combination, they are very effective at uncovering customers' hidden needs.

Repertory grid analysis was developed by psychologists as a way to understand the patterns in which individuals think; to uncover their o-called cognitive maps. This technique is ideal for developing ideas for both new product and services, especially in B2B markets. It only uses one question, asked multiple times, to stimulate customers to compare and contrast their experiences of existing products. Through the process of comparing and contrasting, customers' hidden needs are revealed, which can be used to develop non-incremental product concepts.

Another effective technique for uncovering hidden needs is ethnographic market research, which is based on ideas from anthropology, the social science which studies tribal culture. The techniques of ethnography help us understand culture and are directly applicable to understanding our customers.

In market research, ethnography can unveil latent customer needs; the emotional factors that impact customer satisfaction; and the characteristics of customers that drive product usage.

A common approach is to obtain permission to make videos of customers using existing products, and then conduct a deep analysis of what customers said and what was observed.

For example, Bosch Packaging identified the needs of production employees operating complex production lines. Observation gave deeper insights than simply asking operators.

Lead users are the customers who use products under the most demanding conditions. For example, to understand how better hygiene-related products could be developed for the operating room, 3M studied the requirements of field hospitals in combat zones. In demanding situations users often have to modify products to work around their limitations. By looking at such modifications, ideas for product improvements for the broader market can be obtained.

During the last three years I have worked several times with H&T Presspart. It is a fascinating company — a true hidden champion. To address its ambitious organic growth targets, H&T Presspart has built its capability to innovate during the last years. Part of this work has been a focus on customers' hidden needs and I am sure that this will enable H&T Presspart to develop innovative products that delight customers and contribute to the success of the Group.

POWDAIR PLUS

IN DEVELOPING MARKETS, WHERE DEMAND FOR RESPIRATORY TREATMENTS IS GROWING RAPIDLY, THERE'S AN INCREASING NEED TO OFFER MORE CHOICE TO PATIENTS WHO USE A DRY POWDER INHALER (DPI).

PowdAir Plus, developed in partnership with Hovione Technology, is a patented capsule-based DPI, ideal for these markets because of its advanced simplicity, ease of use and affordability.

Most other DPIs have been designed for developed markets and incorporate multiple components and complex mechanics. In contrast, PowdAir Plus is a complete unit with no metal or separate parts. Neat and compact, its novel all-plastic, four-component design minimises manufacturing assembly and production costs, while improving the device's resilience to frequent use.

The sleek design of PowdAir Plus makes the inhaler very easy to use. It's highly portable, and delivers an effective dose of medication with each capsule. Compatible with all capsule types (gelatine and HPMC) in size 3, it can be used with any dry powder medicines.

A particularly useful design feature is the capsule automatically pierces when the capsule tray is closed. Patients don't need to pierce the capsule themselves, so using the inhaler is simpler, and there's no risk of getting the wrong dose.

PowdAir PLUS

QUANTUM™ DOSE INDICATOR

H&T PRESSPART'S QUANTUM™ DOSE INDICATOR IS THE VERY FIRST ON-CAN METERED-DOSE INHALER (MDI) END-OF-LIFE SOLUTION, ENSURING PATIENTS DON'T RUN OUT OF THEIR MEDICATION.

Quantum has an arrow printed on to the bottom of the MDI canister which a patient can use either with a smartphone app or card, to give an indication of how much medication is left in the MDI.

Unlike other dose counter and dose indicator systems, Quantum does not require any changes to a customer's actuator or packaging and filling lines meaning Quantum can be brought to market relatively quickly.

For patients, Quantum provides a convenient and easy way for them to monitor the amount of drug left in their MDI. Quantum also has no moving parts, making it extremely reliable to use.

Quantum's App provides the patient with a healthcare management system which can be used to track usage and monitor compliance, as well as create reports which can be shared with a physician.

QUANTUM™
DOSE INDICATOR

eMDI™

H&T PRESSPART HAVE PARTNERED WITH COHERO HEALTH™ TO DEVELOP THE FIRST MARKET-READY, FULLY EMBEDDED AND CONNECTED METERED-DOSE INHALER.

By tracking and recording data on the use of medications, and sharing it with patients and physicians via a mobile or web app, H&T Presspart's eMDI™ powered by Cohero™ enables pharmaceutical manufacturers to bring the best possible care to those with asthma and COPD.

The eMDI™ improves patient's adherence to prescribed medication doses, encourages self-care, and helps health professionals maintain real-time monitoring. The device integrates with Cohero Health's™ BreatheSmart®, the only respiratory disease management platform that enables tracking of both controller and rescue medications, and measures lung function with clinical accuracy. Therewith it can transfer the data wirelessly to a smart phone app.

DOSE BY DOSE COUNTING SOLUTIONS

H&T PRESSPART OFFERS DOSE BY DOSE COUNTING SOLUTIONS TO HELP IMPROVE PATIENT SAFETY AND QUALITY OF LIFE.

H&T Presspart offer a mechanical dose-counting system – a licensed design from 3M™ – suitable for any generic or new chemical entity development and compatible with all marketed pressurised metered-dose inhaler (MDI) valves. This technology was the first integrated dose counter available for third-party developments.

The dose counter, along with the eMDI™ and Quantum™, make up H&T Presspart's range of dose counting and end of life indication products for our customers.

Available as a 120 dose counter or 200 dose indicator, our range of counters can be incorporated into our standard range of MDI actuators.

H&T Presspart can also provide testing and support for any dose counter product developments through our Inhalation Product Technology Centre (IPTC).

CAN-IN-CAN TECHNOLOGY

CAN-IN-CAN TECHNOLOGY WAS A PRODUCT WHICH SUCCESSFULLY PASSED THE GATES OF H&T PRESSPART'S STAGE-GATE PROCESS AND IS NOW BEING COMMERCIALLY SOLD.

Can-in-Can technology allows the customer to have metered-dose inhaler (MDI) canisters with smaller fill volumes, without changing the outer shell – ideal for sample products and line extensions.

As its name suggests, Can-in-Can is a small inner can, assembled inside an outer can shell. So you can reduce volume and fill weight in a standard size MDI can and MDI actuator, without making major changes to your filling lines.

The outer can neck profile contains the inner can while keeping the outer dimensions of the assembled system the same as the comparable H&T Presspart standard product.

If needed, you can specify a vent hole in the outer can as an optional safety feature, which works by evacuating the contents of the can in to the atmosphere in case of leakage.

INHALATION PRODUCT TECHNOLOGY CENTRE

IN 2012 H&T PRESSPART CREATED THE INHALATION PRODUCT TECHNOLOGY CENTRE (IPTC), A SPECIALIST R&D FACILITY TO SUPPORT OUR OWN STRATEGIC PROJECTS, AND THOSE OF OUR PHARMACEUTICAL CUSTOMERS.

IPTC provides our customers with bespoke strategic and operational project support in three key areas of developing new devices and components, developing new products, and analytical support. The key capabilities of the Inhalation Product Technology Centre are:

- Formulation support, testing and optimisation
- Inhalation device design, development and customisation
- Component or device performance evaluation, screening and optimisation
- In-vitro characterisation
- Analytical development
- Regulatory support

With H&T Presspart's long-standing expertise and in-depth technical understanding of metered-dose inhaler and dry powder inhaler components and performance, IPTC can help minimise our customers development cycles, providing a faster route to market.

With easy access to inhalation devices and components, we can offer fast turnaround times and end-to-end project support, for custom devices and generics.

PROCESS INNOVATION

AS THE MARKET LEADER IN OUR INDUSTRY, H&T PRESSPART HAS A LONG HISTORY OF PROCESS INNOVATION.

H&T PRESSPART CONTINUALLY STRIVES TO IMPLEMENT PROCESS INNOVATIONS THAT WILL HELP IMPROVE OUR BUSINESS FOR THE BENEFIT OF OUR EMPLOYEES AND OUR CUSTOMERS.

PLASMA TECHNOLOGY

AN INNOVATIVE INTERNAL SURFACE TREATMENT FOR METERED-DOSE INHALER (MDI) CANS.

H&T Presspart offers a unique plasma process – manufactured under exclusive, world-wide license from Portal Medical Ltd – for treating the internal surfaces of metered-dose inhaler (MDI) canisters, which ensures the active drug content within the can does not stick to the canister wall. This solves a problem present in many other MDI cans and ensures the patient gets the correct dose.

This fluorocarbon polymerisation (FCP) plasma treatment process – available only from H&T Presspart – improves the surface energy performance of an MDI canister, which enhances drug stability in formulations where interactions with the aluminium substrate can lead to product degradation and reduced shelf life. We've used the process to develop several different plasma treatment options that successfully prevent drug degradation in solution or suspension formulations.

H&T Presspart's plasma treated metered-dose inhaler cans are unique in the terms of the quality of the surface treatment that is achieved, ensuring our cans meet the strict requirements of the pharmaceutical markets.

Over the last two years H&T Presspart Blackburn, along with a number of selected partners, have been developing a new industrialised plasma process for mdi canisters. The new plasma manufacturing cell is based on a modular design, meaning, the output of the cell can be increased quickly and easily as market demand for plasma cans increases.

The new industrialised plasma manufacturing process is a fully automated system incorporating loading, treatment and inspection of the plasma treated cans.

VISION | INSPECTION

STATE-OF-THE ART QUALITY INSPECTION FOR METERED-DOSE INHALER (MDI).

H&T Presspart Blackburn has recently replaced the Vision inspection equipment, located in the stainless steel MDI canister manufacturing cell.

A project to replace the current Vision System began in 2014 due to the equipment being obsolete. The project looked to find a replacement system that matched, or even improved the detection of material defects in the stainless steel MDI cans.

Having reviewed various technologies available on the market, the Vision System was picked because it was identified to be the most effective and efficient solution for identifying defects in the product.

The final selection of the new supplier was chosen based on the fact they specialised in the high speed inspection of metal components.

The new Vision machine, which was installed in quarter one of 2018, uses a metering wheel to separate the cans, which are then fed through the machine on a stainless steel conveyor.

Fifteen cameras, covering the sidewall, neck, rim, internals, and base inspect the canisters at a speed of 200 parts per minute.

H&T Presspart's process innovation has allowed us to introduce a Vision System that now delivers an inspection system that features three times more cameras, is more accurate, and can run at a higher speed than previously.

ACTUATOR MANUFACTURING

A NEW STATE-OF-THE-ART METERED-DOSE INHALER ACTUATOR MANUFACTURING FACILITY.

H&T Presspart's Tarragona site has recently created a brand new cleanroom facility for the manufacture of metered-dose inhaler actuators, with the commercial production on the first production tool already begun.

In this new cleanroom, H&T Presspart Tarragona has invested a large amount of time and resources in redesigning the existing processes to significantly improve the manufacturing operation. This process innovation has allowed for many improvements within the manufacturing facility including safety, quality, ergonomics, sustainability and maintenance.

One of the biggest changes is the injection moulding area for the MDI actuators, which is now segregated from the assembly area. In the moulding area the environment is temperature and humidity controlled. However, in the assembly area, there is additional particle monitoring which allows the assembly area to be certified as category ISO8, according to ISO 14644-1 and ISO 14698 standards.

This new segregation in environments within the manufacturing process allows the facility to operate with minimal energy consumption while accomplishing all the requirements for our customers and ISO certification.

One of the main achievements of the new clean room facility was to segregate all the manufacturing processes. This has resulted in a manufacturing flow in which there is no possibility of any cross material flow, eliminating the possibility of any interference in the processes traceability.

INNOVATION CULTURE

FAIL FAST AND CHEAP TO SUCCEED SOONER: THE ENTIRE SHOP FLOOR OF OUR BLACKBURN SITE WAS RECENTLY TRAINED IN INNOVATION TO STRENGTHEN THE INNOVATIVE COMPANY CULTURE.

Being successful in product and process innovation requires a customized approach that acknowledges the differences between managing the daily business and driving innovation based on new products and processes. One of several crucial elements of this customized approach is an innovative company culture. To further strengthen the ‘innovation mindset’ at H&T Presspart and H&T Industrial the site in Blackburn decided to train the entire shop floor on innovation.

During several training sessions the attributes of a successful and innovative company culture were discussed (see table below). Hands-on exercises demonstrated the value of prototyping including a powerful learning process based on early and cheap failures during a new product development process. Everybody had a lot of fun and is fully committed to further strengthen the ‘innovation culture” through future contributions.

Key Attributes of a Culture of Innovation[1]

Attribute	Ways to build this attribute
Customer-centricity	• Be strongly focused on serving customer needs • Train employees in methods to identify customer needs • Identify company values and preferred behaviours
Openess to new ideas	• Ensure high levels of trust • Use appropriate (not excessive) levels of control • Use experimentation constantly
Effective cross-funtional teams	• Recruit and work with creative people • Build collaboration and diverse cross-functional teams • Reserve and protect the time needed for innovation • Ensure effective commuications
Well-defined processes	• Have ways to generate ideas • Select ideas focusing more on growth than costs • Create flexible but fast implementation processes
Risk tolerance	• Actively avoid risk aversion • Focus on learning rather than blame
Reward and recognition	• Provide the opportunity to join challenging projects • Give full and regular recognition
Effective leadership	• Provide a clear vision on the role of innovation • Set appropriate boudaries • Show executive sponsorship and participation • Give a commitment to innovation in terms of time

[1]Based on Goffin and Mitchell, Innovation Management: Effective Strategy and Implementation, Palgrave (2017)

We welcome our customers to come and visit our Inhalation Product Technology Centre and talk about new and innovative ways to deliver your drugs to patients.

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PRODUCT & PROCESS INNOVATION

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