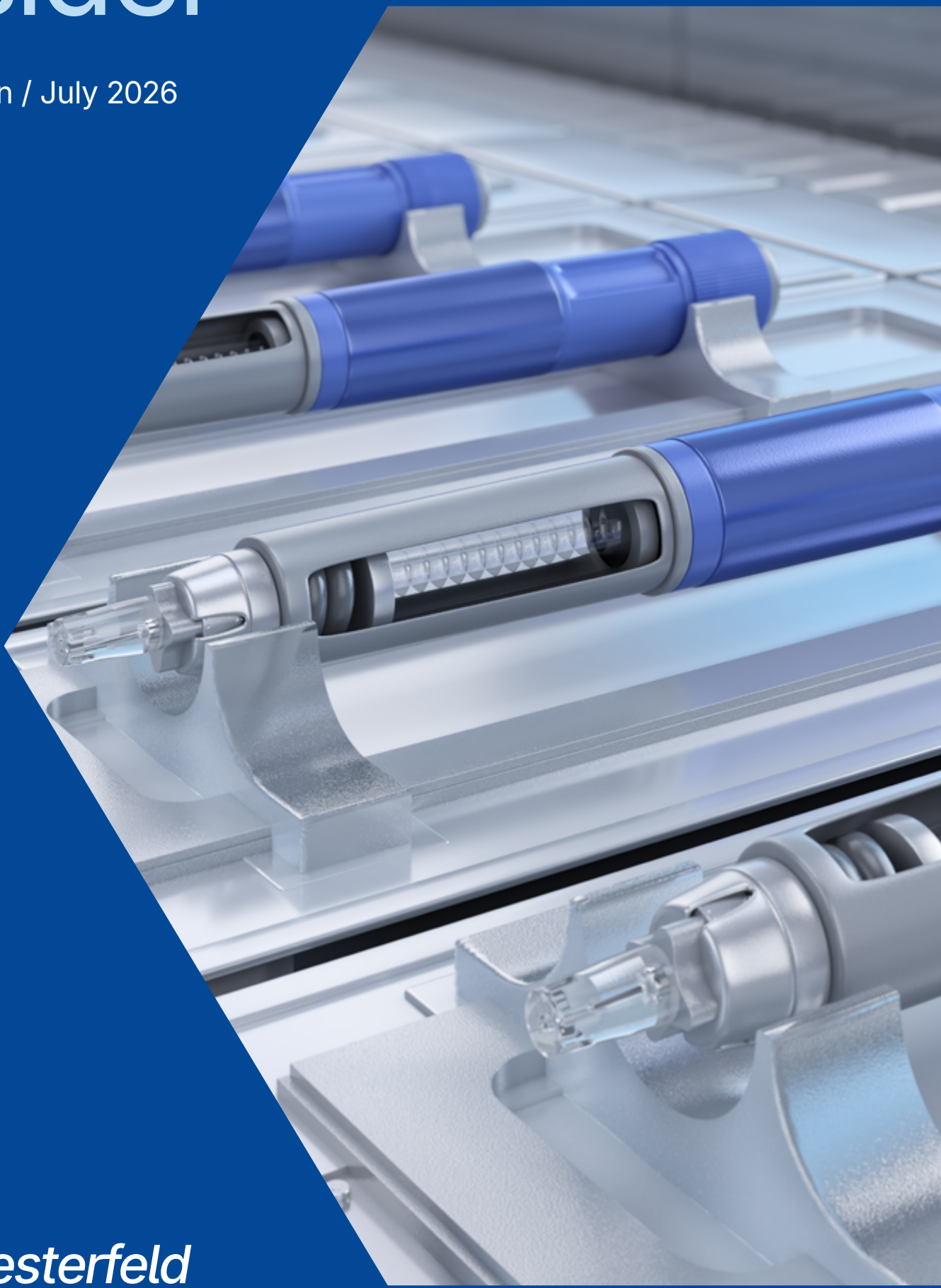
MedTech Materials Insider

Q2 Edition / July 2026



Biesterfeld

Agenda

Editorial

Why Supplier Collaboration Matters More Than Ever

The MedTech industry is entering a period of rapid transformation. Increasing regulatory expectations, sustainability requirements and global supply chain pressures are reshaping how medical devices are designed, manufactured and delivered.

In this complex environment, innovation rarely happens in isolation. Instead, it emerges from strong collaboration between material suppliers, device manufacturers and channel partners.

With Medtech Materials Insider magazine, the Biesterfeld LifeSciences business unit aims to strengthen these connections. This publication brings together insights from our suppliers, our technical experts and the broader MedTech ecosystem to support better material selection and enable your next-generation product development.

In this first issue, we highlight emerging trends in drug delivery devices, explore the role of advanced medical polymers and share perspectives from our partners and industry events.

Our objective is simple: to provide practical insights that help translate material science into real medical innovation.

Jennifer Gemo
Global Strategic Marketing Manager
Biesterfeld LifeSciences

Supplier Insider

Industry Perspectives from Dymax & LG Chem

In this issue, we spoke with experts from Dymax and LG Chem, two key partners supporting innovation respectively in medical bonding technologies and medical grade polymers.

Topics discussed include:

- The biggest challenges faced by device manufacturers today
- Emerging trends in drug-delivery device design
- The growing role of advanced medical polymers and adhesives
- Sustainability and regulatory adaptation in materials development
- The importance of collaboration between suppliers and distribution partners

As drug-delivery systems evolve toward more compact, patient-friendly and connected devices, materials and bonding technologies must meet increasingly demanding requirements. Our partners share how they are supporting this transformation.

Interview: Michelle Evanoski

Global Medical Business Development Lead, Dymax Corporation

What challenges do manufacturers of drug delivery devices face today?

Prefilled syringes, autoinjectors, and infusion sets often combine multiple components, dissimilar substrates, and electronics within small assemblies. Achieving reliable bonds between different materials while maintaining mechanical integrity, performance, and fluid sealing characteristics is a recurring challenge manufacturers face. At the same time, manufacturers must ensure that bonded assemblies maintain performance after sterilization processes such as ethylene oxide (EtO) or gamma irradiation while still supporting highly repeatable high-volume manufacturing.

Needle hub-to-cannula bonding is a common example. The stainless steel cannula must be permanently secured within a polymer hub while maintaining consistent pull strength and preventing leakage of medication or bodily fluids. Joint design, adhesive rheology, and surface preparation all play a role in ensuring consistent performance under mechanical stress during insertion and withdrawal.

Material selection can also complicate the joining process. Hard-to-bond plastics such as polypropylene (PP), polyethylene (PE), and cyclic olefin copolymers (COC/COP) are widely used for drug reservoirs, cartridges, and fluid-contact components because of their chemical resistance and compatibility with pharmaceutical formulations. However, their low surface energy can make adhesion challenging. Surface treatments such as plasma or corona discharge are often used to improve wettability and enable strong adhesive bonding.

A key barrier to successful bonding is overlooking all aspects of end-use requirements and failing to anticipate assembly challenges early in the design process. Proper material selection and following proper testing protocols can help identify and reduce bond failure, bottlenecks, variable performance, and material waste.

What major trends do you currently see in bonding technologies in drug delivery devices?

In high-volume automated production environments light-curable adhesives are widely used because their rapid curing under UV or LED light (typically 365–405 nm) supports precise dispensing, tight process control, and efficient high-throughput manufacturing.

> "A key trend is the growing importance of process validation and inspection."

As assemblies become more intricate, manufacturers are placing greater emphasis on verifying adhesive placement and cure during production. Adhesives incorporating inspection features such as color-change indicators or fluorescence allow bond lines to be confirmed either visually or through automated inspection systems. These features support in-line inspection and help reduce the risk of assembly defects in high-volume manufacturing.

Miniaturization is also influencing adhesive selection. Devices such as continuous glucose monitors and wearable insulin injectors integrate sensors, electronics, and fluid delivery mechanisms within very compact housings. Smaller bond areas and tighter tolerances require adhesives with controlled viscosity and reliable curing performance that do not introduce thermal stress, misalignment, or deviation of sensitive components that may result in failure.

What differentiates your medical adhesive portfolio?

The Dymax MD® line of medical adhesives cures in seconds upon exposure to LED or UV/Visible light. Since they cure on demand, components can be adjusted as needed prior to light curing exposure, critical for exact alignment in end-user parts, or cured immediately to maintain exact positioning.

Dymax MD® adhesives not only form bonds that are often stronger than the substrates they are applied to, but they must also meet biocompatibility requirements such as ISO 10993. Initial evaluation typically includes in-vitro cytotoxicity, with further testing, such as hemolysis, systemic toxicity, irritation, implantation, and sensitization, performed as appropriate based on the intended end use, market, and application.

Unlike epoxies and other two-component systems, Dymax adhesives are 1-part chemistries that cure when exposed to the proper wavelength and intensity, so no mixing is required to activate the curing process. They are also formulated without solvents, reducing harmful fumes and environmental impact, lowering energy and material costs through faster curing and minimal waste, and providing a cleaner, safer application process

Compatibility with the materials commonly used in drug delivery devices may involve dissimilar, UV-inhibited and tinted plastics, or hard-to-bond cyclic olefin copolymers (COC/COP), along with other rigid and flexible substrates. Dymax formulations provide reliable adhesion across different applications while accommodating different joint geometries, dispensing methods, and assembly processes.

Many Dymax products are designed with See-Cure color-change indicators and red or blue fluorescence so manufacturers can visually confirm adhesive placement and cure, verify bond line integrity, and quickly perform in-line testing and quality inspection. These attributes help reduce the risk of bonding defects and support automated vision and sensing systems while increasing assembly speed and throughput in high-volume production environments.

In response to evolving regulatory requirements, Dymax is continuously evaluating and advancing its portfolio to align with stringent EU MDR and other regulatory frameworks while still maintaining critical performance. This includes a refreshed series of TPO-Free alternatives to some of their top performing products, many of which are already available. Additionally, there are IBOA-free adhesives specifically designed for medical wearables, such as CGMs and insulin pumps that are in close proximity to the skin.

What innovations are coming next?

One area of development involves adhesive chemistries designed to address evolving regulatory expectations. In particular, the industry is seeing increased interest in formulations that eliminate certain photoinitiators like TPO and materials of concern such as IBOA while maintaining curing performance and manufacturing efficiency.

Other new innovations, not specific to drug delivery devices, are hybrid light curable materials. These formulations combine the exceptional physical and performance properties of Dymax light-curable adhesives and the rapid moisture/contact cure of anionics. The contact curing feature allows bonding to a broad range of substrates, including opaque and light-blocking materials, and in shadow areas not reachable by light.

What drives the adoption of these technologies today?

> Adoption is largely driven by manufacturing efficiency and process control.

Drug delivery devices are typically produced in high volumes, and manufacturers need bonding technologies that support consistent, repeatable assembly processes.

Light-curable adhesives enable curing on demand when exposed to the appropriate wavelength and intensity of light, often using UV or LED curing systems operating around 365–405 nm. This allows manufacturers to reduce curing times from minutes or hours to seconds and minimize work-in-process delays.

Another important factor is quality assurance. Adhesive systems that support in-line inspection and cure confirmation provide manufacturers with greater confidence that bond lines have been applied correctly and that curing has been completed before devices leave the production line.

How do biocompatibility and performance requirements influence adhesive selection for medical assemblies?

Biocompatibility and performance requirements are both critical factors in adhesive selection for medical device assemblies. From a biocompatibility standpoint, adhesives must meet standards such as ISO 10993, ensuring they are safe for their intended use, particularly in devices with direct or indirect patient contact.

Adhesives must also deliver reliable performance, including adequate bond strength, flexibility, chemical resistance, and durability under environmental stresses such as sterilization, moisture, and thermal cycling. Ultimately, adhesive selection is a risk-based, application-driven process, where materials are chosen not only for their ability to pass biocompatibility testing, but for their capacity to maintain performance throughout the device lifecycle.

What role do distributors like Biesterfeld play in supporting customers?

Distribution partners play an important role in connecting device manufacturers with specialized materials and technical expertise. They often act as a local technical interface between suppliers and customers, supporting discussions around material selection, process development, and application requirements.

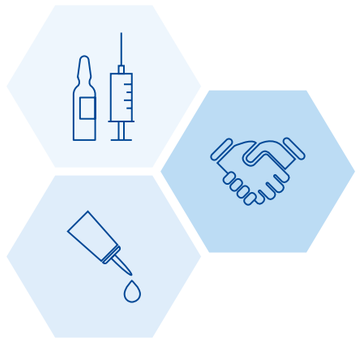
By maintaining strong relationships with both manufacturers and suppliers, distributors can help identify appropriate solutions for specific applications and support device development and validation efforts.

What does the Dymax–Biesterfeld partnership bring to customers?

The collaboration between Dymax and Biesterfeld is built on many years of strong partnership that combines adhesive technology expertise with regional market knowledge and technical engagement. We have enabled many device manufacturers to access specialized bonding technologies while benefiting from and make the best of local technical support during development, validation, and production.

Working together allows both organizations us to support customers as they address the evolving challenges of drug delivery device design and manufacturing.

Interviewer: Caroline Heinrich, Product Manager Biesterfeld LifeSciences – Medical Specialties



Interview: Marvin Uwas

Senior Manager (EMEA), LG Chem

What challenges do customers share with you most often?

The challenges customers most frequently share with me relate to balancing performance, compliance, and manufacturability. Many medical device developers are under pressure to meet strict regulatory requirements while also pushing for more innovative, lightweight, and cost efficient designs.

In addition, customers often struggle with selecting materials that deliver the right combination of mechanical strength, chemical resistance, and processing stability, especially for autoinjectors, inhalers, and connected drug delivery systems.

Ensuring global supply reliability and consistent quality across different regions is another recurring concern, particularly as product lifecycles become more complex.

What major trends do you currently see in ABS technologies in drug delivery devices?

Today, I see a clear shift toward higher performance medical ABS grades engineered for improved chemical resistance, dimensional stability, and long term durability.

> "Drug delivery devices are becoming more sophisticated, incorporating spring mechanisms, embedded electronics, connectivity features, and reusable components – all of which demand materials with tighter tolerances and improved robustness."

Another trend is the growing need for materials suitable for multi component assemblies, where ABS must bond reliably with PC, TPE, or metal components. At the same time, there is increasing interest in sustainability aligned solutions, such as materials designed for recyclability or lower carbon manufacturing.

Overall, ABS is evolving from a commodity polymer into a high function, engineered material for modern medical device architectures.

What differentiates your medical grade portfolio?

Our medical grade ABS portfolio is differentiated by three core factors: high consistency, regulatory readiness, and engineered performance. Each grade is supported by robust biocompatibility documentation, long term formulation control, and security of supply systems designed for the medical industry.

Technically, the portfolio offers enhanced flow properties, excellent surface quality, and excellent mechanical strength, enabling precise molding and stable performance in demanding device environments. In addition, we provide customers with global technical service, design support, and close collaboration throughout the device development lifecycle – ensuring that our materials not only meet specifications but truly strengthen the reliability of the final product.

What innovations are coming next?

We are currently advancing several innovation tracks. One focus is on next generation ABS solutions with improved chemical resistance, tailored specifically for autoinjector and wearable device housings exposed to aggressive formulations. Another area is lightweight, high rigidity blends designed for miniaturized components that require both strength and dimensional precision.

We are also investing in eco conscious material technologies, including solutions with reduced carbon footprint and materials compatible with circular design strategies. These innovations aim to support the medical industry's transition to more durable, sustainable, and smarter drug delivery systems.

What drives the adoption of your technology today?

Adoption is largely driven by the rising technical requirements of drug delivery devices. Customers need materials that guarantee precision, safety, and regulatory reliability while also enabling modern industrial design and efficient mass production. Our ABS technologies offer predictable performance, high processability, and stable global availability – attributes that are essential for device manufacturers facing competitive timelines and stringent quality expectations.

In short, companies choose our materials because they reduce development risk, streamline regulatory pathways, and deliver consistent performance throughout the lifecycle of the device.

How do you adapt to the regulatory and sustainability demands? Reusable instruments are evolving. How do materials adapt?

We adapt by integrating regulatory compliance and sustainability considerations into the very foundation of our material development strategy. Our medical grades follow strict formulation lock principles, long term change management, and comprehensive regulatory support files to ensure global approval compatibility.

As reusable instruments continue to grow, materials must withstand stronger thermal, mechanical, and chemical stresses. We therefore focus on enhancing heat resistance, durability, and sterilization tolerance, ensuring that our materials maintain performance over repeated cycles. At the same time, we are developing solutions aligned with recyclability and reduced carbon footprint, supporting medical device manufacturers as they navigate new sustainability expectations.

What role do distributors play in your go to market strategy?

Distributors play a critical and strategic role in our go to market approach. They extend our reach by providing regional market insights, local inventory, rapid logistics, and technical guidance. Their close proximity to customers enables faster response times and more hands on support throughout development and production phases.

By partnering with strong distributors, we ensure that customers receive consistent service, reliable supply, and expert technical assistance – no matter where they are located.

What does your collaboration with Biesterfeld bring to your customers?

Our collaboration with Biesterfeld delivers substantial value by combining our advanced material technology with their deep market expertise and customer focused service infrastructure. Biesterfeld offers extensive experience in medical and technical applications, strong technical service capabilities, and a well established supply network across Europe.

For customers, this means seamless access to our medical grade materials, faster technical support, efficient sample management, and a partner who understands both the polymer landscape and the regulatory environment. Together, we provide a highly reliable, solution oriented partnership that supports customers from the earliest design stages to full scale production.

Interviewer: Saskia Wiebel, Global Segment Manager LifeSciences – Medical Polymers

Application Insider

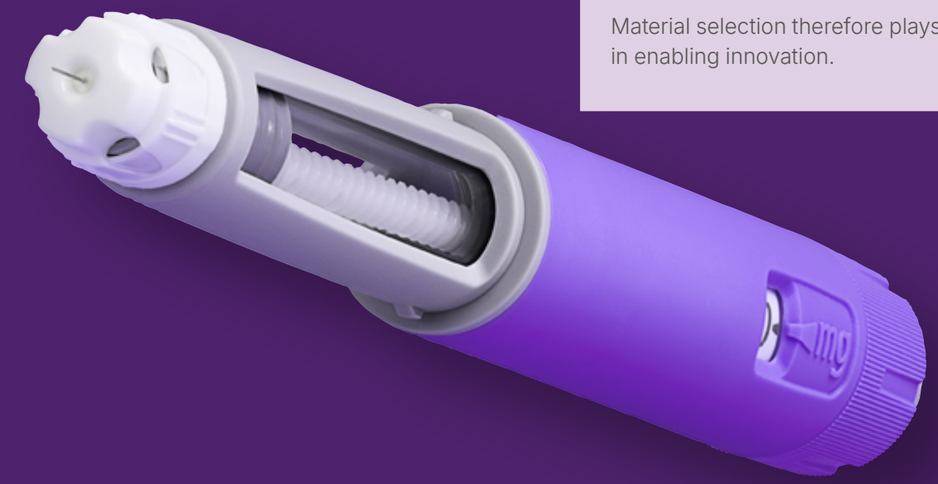
Drug Delivery Devices: A Rapidly Transforming Landscape

Chronic disease prevalence, biologics growth and home care adoption are fueling demand for intuitive, reliable and safe drug delivery systems such as auto-injectors, insulin pens, wearable pumps and inhalers.

What's Driving Change

- Shift to self administration
- More compact, ergonomic and reusable platforms
- Sustainability pressures (PFAS free, BPA free, recyclable)
- Lightweight thin wall and metal free designs

Material selection therefore plays a critical role in enabling innovation.



The Crucial Role of Medical Polymers

Medical polymers define the functionality, safety and reliability of modern delivery systems.

> Medical polymers are enabling the next generation of patient-friendly drug delivery devices.

Saskia Wiebel, Global Segment Manager LifeSciences - Medical Polymerss

Key Material Contributions

- Precision and stability for autoinjectors, pens, pumps
- Thin wall moldability enabling compact form factors
- Improved ergonomics for safer self-administration
- Controlled extractables/leachables for drug compatibility
- Scalable, high precision manufacturing
- Support for sustainable and reusable concepts

Biesterfeld Role and Offering for Drug Delivery Devices

A cross-portfolio approach to accelarate device innovation

Biesterfeld LifeSciences provides a unique portfolio covering **thermoplastics**, **elastomers**, **thermosets**, **bonding technologies and specialty materials** suitable for injectors, inhalers, infusion systems, wearables and surgical components.

Biesterfeld dedicated healthcare team brings:

- Technical expertise
- Market knowledge
- Regulatory and quality support
- Strong OEM, CDMO and value-chain engagement from the design phase

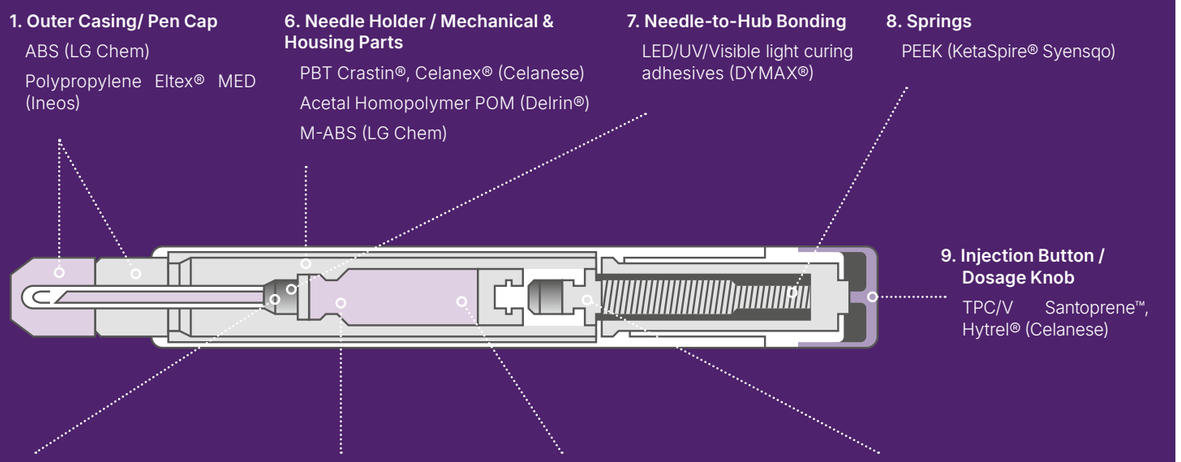
Biesterfeld enables early stage design confidence through specification support, documentation readiness and secure supply.

> As the link between material suppliers and the device industry, Biesterfeld places a strong focus on understanding key market needs. These insights enable us to create comprehensive solution portfolios and provide customers with reliable, expert material guidance.

Saskia Wiebel, Global Segment Manager LifeSciences – Medical Polymers

Below is a representation of the key portfolio Biesterfeld offers in Medical Devices that is relevant for drug delivery devices like Injectors pens.

Inside View of Injector Pens



1. Outer Casing/ Pen Cap
ABS (LG Chem)
Polypropylene Eltex® MED (Ineos)

2. Pre-Filled Cartridge Plunger
Chlorobutyl rubber, Bromobutyl rubber (BIIR) (Exxon™)

3. Insuline Reservoir
ViviOn™ CBC (USI)

4. Needle, Plunger, Reservoir Lubrification
Silicone Oil / Emulsion (Liveo™)

5. Drive Mechanism, Threaded Screw, Ratchet
Acetal Homopolymer POM (Delrin®)

6. Needle Holder / Mechanical & Housing Parts
PBT Crastin®, Celanex® (Celanese)
Acetal Homopolymer POM (Delrin®)
M-ABS (LG Chem)

7. Needle-to-Hub Bonding
LED/UV/Visible light curing adhesives (DYMAX®)

8. Springs
PEEK (KetaSpire® Syensqo)

9. Injection Button / Dosage Knob
TPC/V Santoprene™, Hytrel® (Celanese)

Celanese
The chemistry inside innovation™

Delrin®

Manufactured by
LG Chem

SYENSQO

USI

ExxonMobil

DYMAX®

DUPONT
LIVEO™

Spotlight
Drug Delivery
Devices

Product Insider

Acrylonitrile Butadiene Styrene (ABS) in Modern Drug-Delivery Devices

Acrylonitrile Butadiene Styrene (ABS) remains one of the most versatile polymers in today's MedTech industry, **Its makes it particularly suitable for drug-delivery devices and diagnostic equipment**.

As healthcare shifts toward home care, self administration, and compact digital diagnostics, ABS provide a good balance of impact strength, dimensional stability, and processing versatility

Medical grade ABS grades now offer enhanced biocompatibility, chemical resistance, and consistent formulations that fully support ISO 10993 and USP Class VI requirements – critical for devices that interface with clinicians, patients, and sensitive pharmaceuticals.

The breadth of ABS applications in MedTech underscores its unique adaptability

- It is used in **needle free injection devices and insulin pen housings**, where resistance to cleaning agents, sterilization, and repeated mechanical loads is essential.
- Transparent and high flow ABS grades enable complex, thin wall parts such as **Luer locks, connectors, and spikes**, providing clarity, toughness, and secure drug delivery pathways.
- ABS can form the **structural housings of inhalers, blood pressure monitors, and defibrillators**, where impact strength, thermal endurance, and long term colour stability ensure reliable performance in demanding clinical and home care environments.
- Its ability to support bonding techniques – including ultrasonic welding, solvent bonding, and adhesives – further expands design possibilities for integrated systems.

LG Chem is the leading supplier of ABS globally

LG Chem's supply chain remains resilient even during global disruption. Production at the company's Yeosu, Korea facility continues without capacity restrictions, supported by fully operational warehouse infrastructure.

Lead times to the United States and Europe are steady at 8–10 weeks, providing customers with dependable delivery and enabling predictable planning across markets.

LG Chem TR558A-L Transparent Medical ABS

LG Chem's **TR558A-L** transparent medical-grade ABS is engineered for applications requiring both optical clarity and mechanical robustness.

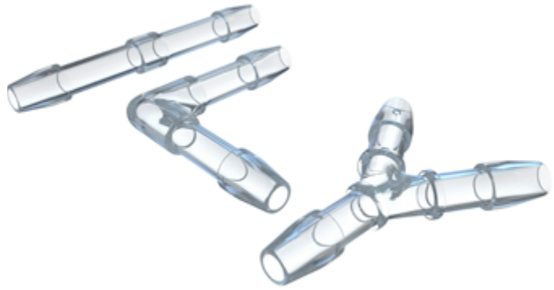
Typical applications include:

- Dose windows in auto-injector pens
- Transparent device components
- Drug-delivery monitoring interfaces
- Connectors

Key features:

- High transparency (90% transmittance)
- Excellent impact resistance
- ISO 10993 and USP Class VI, FDA, REACH, RoHS compliance
- Dedicated medical-grade production

These characteristics allow manufacturers to combine **visual clarity**, **structural reliability and regulatory confidence** in advanced drug-delivery devices.



LG Chem HF380 M – High Flow Medical Grade ABS for Drug Delivery Devices

LG Chem's HF380 M high flow medical grade ABS is engineered to support modern drug delivery systems that demand compact, ergonomic design, efficient processing and strong in use performance.

Typical applications include:

- Thin wall auto injector housings
- Wearable / on body delivery platform components
- Complex, high precision drug delivery device geometries

Key features:

- High flowability for thin wall and complex molding
- Strong mechanical performance
- Excellent chemical resistance for exposure to disinfectants and drug residues
- Stable thermal performance
- Comprehensive regulatory compliance: ISO 10993, USP Class VI, FDA, REACH, RoHS
- Dedicated medical grade production ensuring secure supply and consistent quality
- Dedicated medical-grade production

These attributes support reliable performance, efficient manufacturing and regulatory confidence for next generation on body and handheld drug delivery devices.

Event Insider

Q1 2026 Events: Pharmapack, Making Pharma and MDMWest

Biesterfeld LifeSciences actively participates in major industry conferences to stay at the forefront of emerging technologies and market trends and to foster long-lasting connections.

The following shows were attended by the Medical Polymers and Medical Specialty team in Q1 2026.

- **Pharmapack 2026, January 21–22, 2026 in Paris, France.** The show focused on pharmaceutical packaging and drug delivery innovations, highlighting sustainability, advanced materials, and next generation delivery technologies. It brought together global packaging specialists, device engineers, and pharma leaders to explore future-ready solutions in drug delivery
- **MD&M West 2026, February 3–5 February 2026 in Anaheim, California.** As North America's largest MedTech manufacturing event, it showcased innovations in medical device design, advanced manufacturing, automation, materials, and digital technologies. It served as a key meeting point for engineers, suppliers, and technology leaders shaping the future of medical devices.
- **Making Pharma Spain 2026, February 18–19 February 2026 in Barcelona, Spain.** This new Spanish edition brought together pharmaceutical manufacturers, technology providers, and regulatory experts to focus on drug development, production technologies, quality, and compliance. The show combined an exhibition with a strong scientific and technical seminar programme, highlighting innovations, industry challenges, and solutions for the Spanish and wider European pharma market.

Biesterfeld Key Take-aways from Q1 2026 Events

Early collaboration matters more than ever

- Teams need to align on device, formulation and container choices from the very beginning.
- Choosing between vials, pre-filled seringes (PFS), autoinjectors or wearables requires systematic technical assessment early in development to ensure performance, compatibility and patient usability.
- Co development enables pre selected platform solutions and faster time to market for emerging subcutaneous delivery systems.

High viscosity biologics are raising the bar for engineering

- As an example, thicker formulations are pushing innovation in needles and syringes. Designs now focus on reducing injection effort and improving patient comfort
- Siliconization quality is critical for biologics stability. Baked on silicone layers minimize free droplets, reducing protein aggregation risk and improving compatibility for sensitive molecules.

Delivery solutions are evolving with patient needs

- Home-based subcutaneous (SC) delivery is reshaping drug administration models. Patients increasingly self inject at home, driving demand for safe, intuitive, high volume devices
- Connected devices represent a major opportunity for healthcare. With consumers rapidly adopting wearables, integrated data driven platforms can cut healthcare costs by up to 20%.
- Large volume subcutaneous (≥2–5 mL) delivery is rising quickly, pushing demand for on-body injectors and controlled rate systems to enable intravenous (IV) to sub-cutaneous (SC) migration.
- Multi fixed dose pens are expanding in cardiometabolic care, supporting obesity and diabetes treatments where compliance is key.
- Nasal delivery is growing as a non invasive route for systemic and CNS therapies, driven by improved bioavailability and device precision.

Sustainability is shifting to secondary packaging.

- New regulatory pressure and a $220B market forecast are pushing pharma to optimize materials, recyclability and transport efficiency beyond the primary container.

European Events Lining-up for Q2, 2026

Where we exhibit:

- **CPHI** in Milan, Italy, October 28/30th, 2026

To book a meeting at CPHI, please reach out to: m.lampert@biesterfeld.com

- **Compamed** in Duesseldorf, Germany, November 16/19th, 2026

To book a meeting at Compamed, please reach out to: a.geffken@biesterfeld.com

Where we walk the show

- **Pharma Days** in Geneva, Switzerland, May 27/28th, 2026
- **MedTech Expo** in Birmingham, UK, June 03-04 2026

MedTech Expo in Ulm, Germany, July 1st/2nd, 2026

MedTech Expo in Galway, Ireland, September 23rd/24th, 2026

To book a meeting at **MedTech Expo**, please reach out to: s.wiebel@biesterfeld.com

Biesterfeld Insider

Inside Medical Polymers Business

Connecting Material Science with Medical Innovation

As a specialty distributor in MedTech, the Biesterfeld LifeScience business unit acts as a **bridge between material suppliers and medical device manufacturers**.

Our role is to:

- Build long-lasting relationship with OEMs, molders and material experts
- Translate material innovation into real device applications
- Enable faster product development through early technical engagement
- Support regulatory and documentation processes
- Maintain reliable supply chains and local stock availability

"Through this ecosystem approach, we help customers accelerate innovation while maintaining the highest standards of quality and regulatory compliance."

Saskia Wiebel, Global Segment Manager LifeSciences - Medical Polymers

Biesterfeld LifeSciences business unit reinforces its Medtech play by expanding its portfolio to Medical Polymers

Since mid 2025, Biesterfeld has carved out the medical portion of its plastics business to be included in the LifeSciences BU which is under Hartmut Zeller's leadership.

Hartmut Zeller
Global Business Director LifeSciences

Saskia Wiebel
Global Segment Manager

Eleftherios Asaly
Global Product Manager

The greatest synergy potential arises in particular from:

- overlapping supplier and customer portfolios
- a strong focus on application-oriented laboratory services
- similarly high quality and regulatory requirements
- expanded opportunities for a holistic one-stop-shop approach

Saskia Wiebel leads the business as the Global Segment Manager for Medical Polymers, with the support of Eleftherios Asaly, Global Product Manager and a dedicated team of eight business development managers, spread across Europe.

The Medical Polymer business reinforces Biesterfeld LifeSciences business unit strong market knowledge, wide customer base and dedicated teams and processes and benefits from the expert regulatory and quality team, supporting audits and documentation.

The LifeSciences business unit also leverages Biesterfeld broad infrastructure and capabilities, namely 4 fully equipped global labs, technology partnerships for specific application tests and a product stewardship team, expert in and guidance on chemical safety regulations.

This decision is supported by strong market drivers

The medical polymer market is showing strong and sustained growth“ driven by strong mega trends.

Aging polulation

Increase of chronic diseases, obesity and cancers

Rising health(sick-)care costs

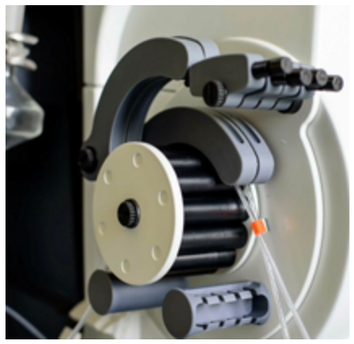
Increased regulatory pressure and sustainability

These healthcare challenges and transformation unlock needs for medical solutions.

As a result, the global healthcare plastics market is estimated at 15 mio. to in 2025, 38 bn. EUR turnover (Europe 9,2 bn. EUR) and experience an annual CAGR of 6-8% (Source: estimated data from several combined market research sources and investor reports).

Biesterfeld offers a rich and expanding portfolio of medical grade polymers targeting high-value medical devices segments:

- Drug Delivery
- Surgical Equipment
- Catheters
- Wearables
- Medical diagnostics
- BioPharma Processing
- Valves and Pumps
- Connectors
- Fluid Handling Tools
- Medical Packaging



Below is a list of the key chemistry, world-renowned principals and flagship brands offered by the Biesterfeld LifeSciences business unit. For country availability, please contact us at medical@biesterfeld.com

Thermoset	Silicones Acrylated Urethanes	DuPont™ Liveo™ adhesives, elastomers and coatings Dymax MD® adhesives
High Performance	PEEK PAEK PPS PPSU PSU PESU LCP CBC	KetaSpire® Syensqo, Victrex™ AvaSpire® Syensqo Ryton® Syensqo Radel® Syensqo Udel® Syensqo Veradel® Syensqo Vectra®, Zenite® Celanese ViviOn™ USI
Engineering Polymers	PC TPC TPU TPV PBT PA6.6, 6.12 POM HOMO PET-G	LG Chem, Wonderlite® Chimei Hytrel® Celanese Elastollan® BASF Santoprene® Celanese Celanex® Celanese, Crastin® Celanese Zytel® Celanese Delrin® Ecotria®, SkyPet® SK Chemicals, Ecozen® SK Chemicals SkyGreen® SK Chemical
Standard Polymers	SAN ABS, m-ABS EVAC PP LDPE HDPE	Kibisan® Chimei Polylac® Chimei, LG Ateva® Celanese Eltex® Ineos, Tatren® Mol Industries Eltex® Ineos, Tipolen® Mol Industries Eltex® Ineos, Tipeline® Mol Industries
Others	CIIR BIIR	Exxon™ bromobutyl rubber, Exxon™ chlorobutyl rubber

Learn more about our solutions:

Inside the Biesterfeld LifeSciences Quality & Regulatory team

> At Biesterfeld, quality is more than a requirement – it is a core commitment that shapes how we work, how we partner with suppliers, and how we support our customers in highly regulated market.

Dr. Julia Schmid, Head of Quality & Regulatory

Key Role and Responsibilities

The Quality & Regulatory (Q&R) team is the key interface between regulatory requirements, internal processes and expectations of customers for our API, pharma, medical polymers and medical specialty businesses.

Our Quality Management is built on an integrated Quality Management System designed to ensure consistent performance across all operations. It includes internationally recognized certifications such as ISO 9001 – ensuring globally aligned quality processes.

Alongside our ISO certification, Biesterfeld voluntarily chooses to be audited by an independent third party according to GDP standards. This reflects our commitment to meeting the elevated requirements of the pharma and medical device sectors.

The Q&R team carries a broad set of responsibilities that ensure Biesterfeld's healthcare activities operate reliably, safely and in full compliance with regulatory expectations.

Their work begins with maintaining the stability of our quality system, i.e. that products and processes remain controlled, documented and traceable. This includes:

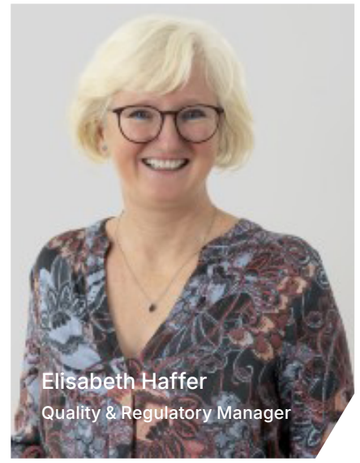
- The careful qualification of suppliers and service providers
- Ensuring that every partner in our supply chain meets the standards required for handling sensitive healthcare products
- Overseeing batch release processes, and managing computer system validations
- Steering risk management activities, assessing potential gaps or vulnerabilities and implementing measures to minimize them
- Maintenance of the CEP for Guaifenesin, ensuring that regulatory documentation stays current and aligned with external requirements

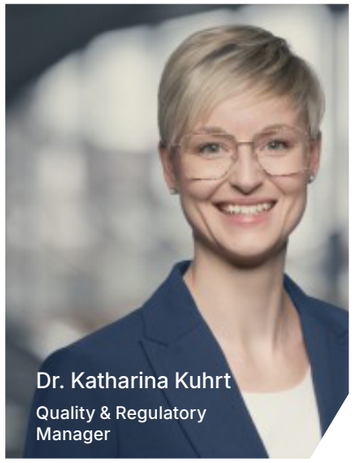
In addition to maintaining internal system integrity, the Q&R team serves as a key partner to our customers.

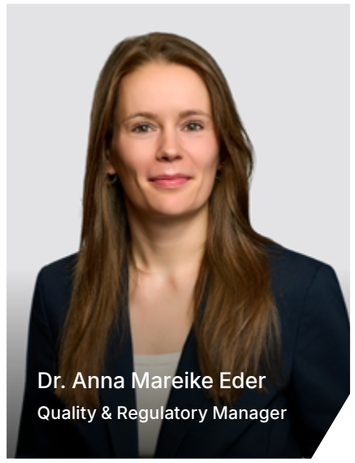
- They prepare and negotiate quality agreements that define mutual expectations, enabling transparent and compliant collaborations.
- When customers seek regulatory clarification, documentation, or product related quality information, the team provides structured and reliable support.
- They also coordinate and respond to audit requests, ensuring that customers receive the insights they need into our or our suppliers operational processes.
- They manage internal and external change notifications
- They prepare supply chain documentation including detailed questionnaires to understand the final use of the materials, enabling customers to meet their own compliance obligations and regulatory filings.

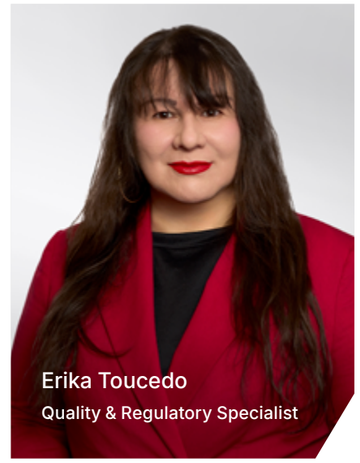
Taken together, these responsibilities position the Q&R team as both guardians of system stability and trusted partners to our customers — ensuring compliance, transparency and reliable quality across every step of the value chain.

Our Key Q&R Team Members









Contact:

bsc.quality@biesterfeld.com

Want to be featured in our next issue?
Want Biesterfeld to address specific topics?

We invite our OEM partners, processors and suppliers to share their thoughts.
Contact us at: **Medical@biesterfeld.com**

Please scan, to subscribe for our

LinkedIn LifeSciences Focus Page

Medical Newsletter

Published by:

Biesterfeld SE
Ferdinandstrasse 41
20095 Hamburg
www.biesterfeld.com

July 2026

Imprint: Biesterfeld Spezialchemie GmbH, Ferdinandstrasse 41, 20095 Hamburg, Germany, www.biesterfeld.com | Registered Office: Hamburg, Commercial | Register: Hamburg, HRB 189926, VAT ID DE196930661 | Managing Directors: Peter Wilkes | Our raw material information, data and graphics was obtained from the records of our raw material suppliers. Local availability of products might difer from country to country.