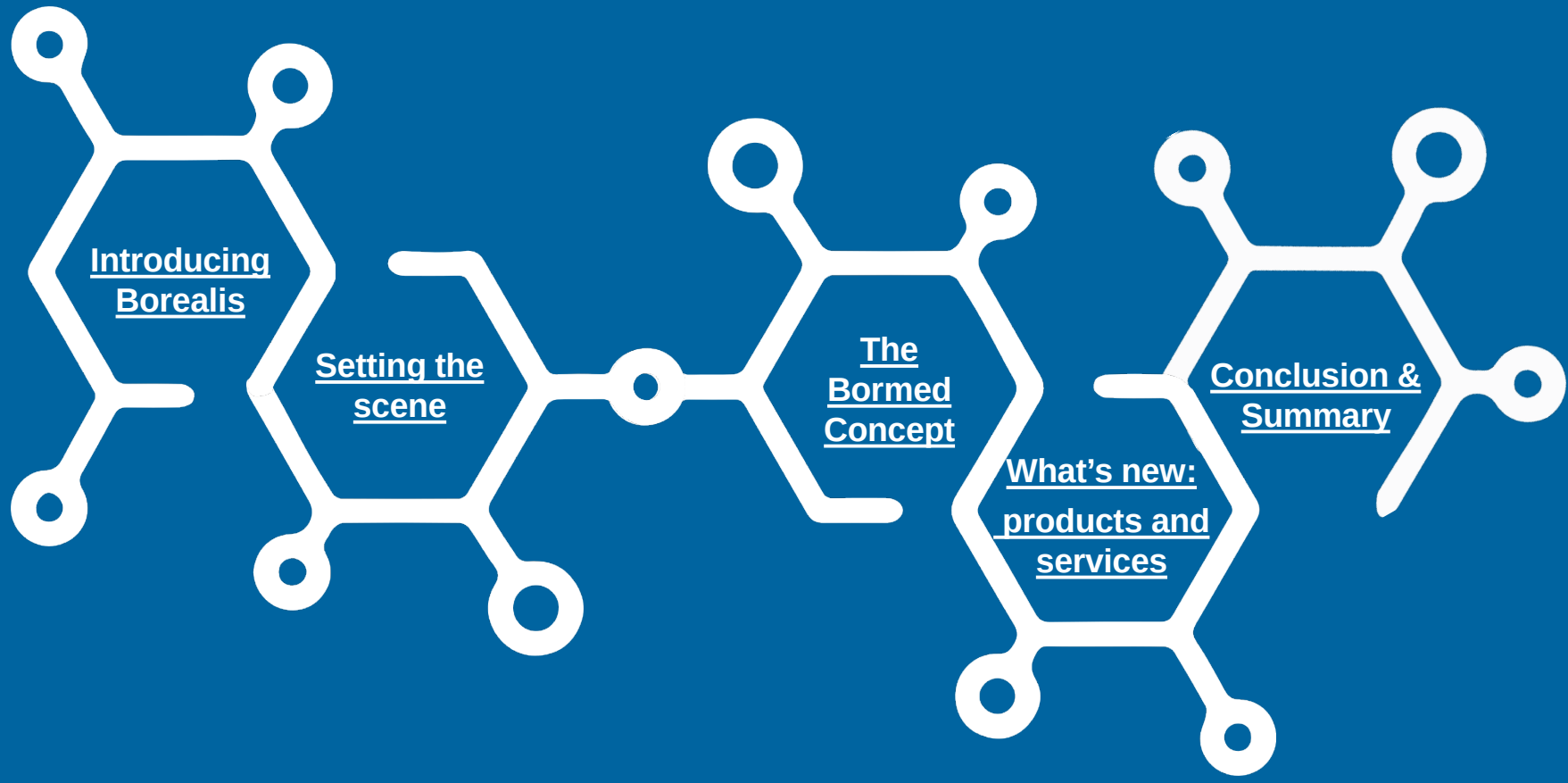
Bormed™ - our global approach to the Healthcare Industry

BOREALIS

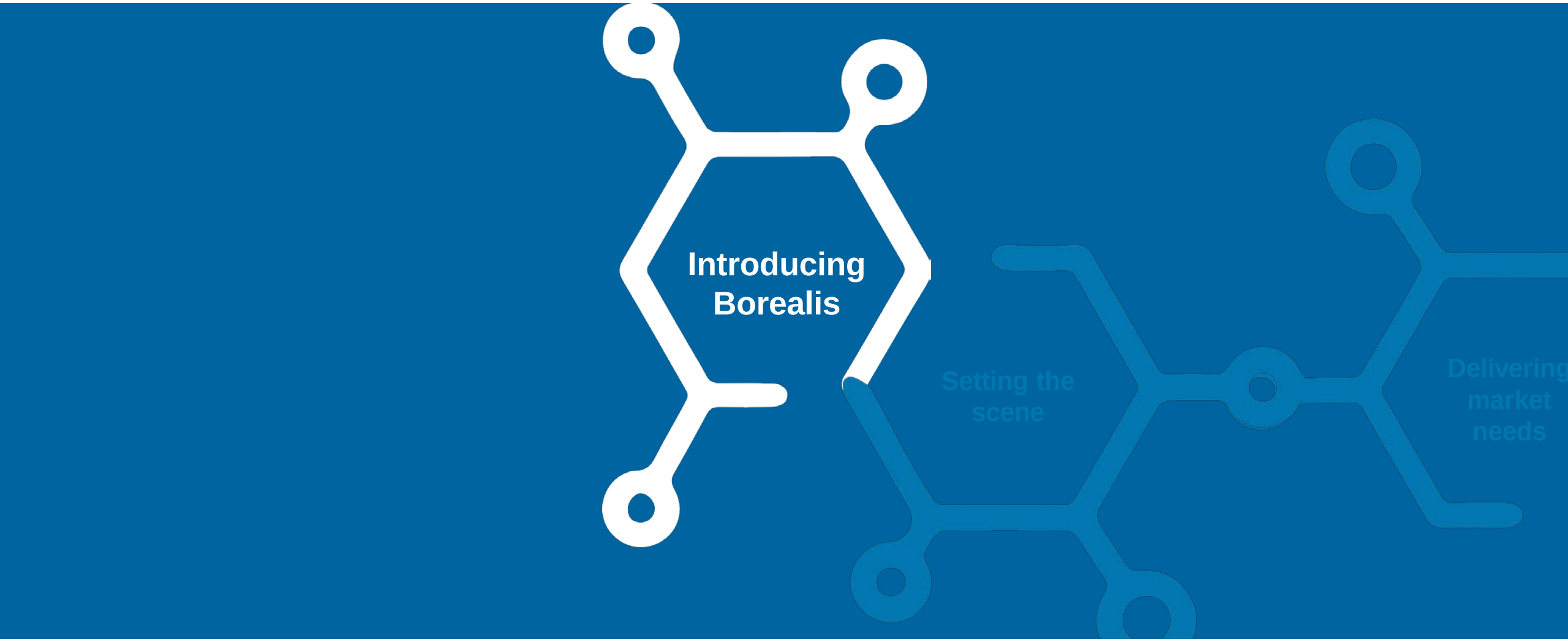
بروج
Borouge

Overview



BOREALIS Borouge

Introducing Borealis



Borealis at a glance

Worldwide

Head Office in **Vienna**, Austria.
Operating on **five continents**
in **120 countries**

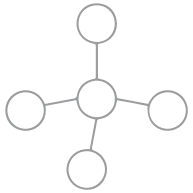
Market Position

#2 among polyolefin
producers in **Europe**

Employees

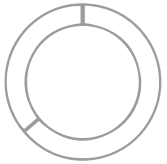
More than
6,900 employees

Line of Business



Production and distribution of
polyolefins, **base chemicals**
and **fertilizers**

Ownership Structure



64% Mubadala, United Arab
Emirates / **36%** OMV, Austria

Financial figures

Net profit 2019 – **MEUR 827**
Net sales 2019 – EUR 8.1 billion

Joint Venture

Borouge – the world's largest
integrated polyolefin complex
in Ruwais, UAE

Joint Venture

Bayport Polymers – brings
Borstar® technology to American
polyethylene markets

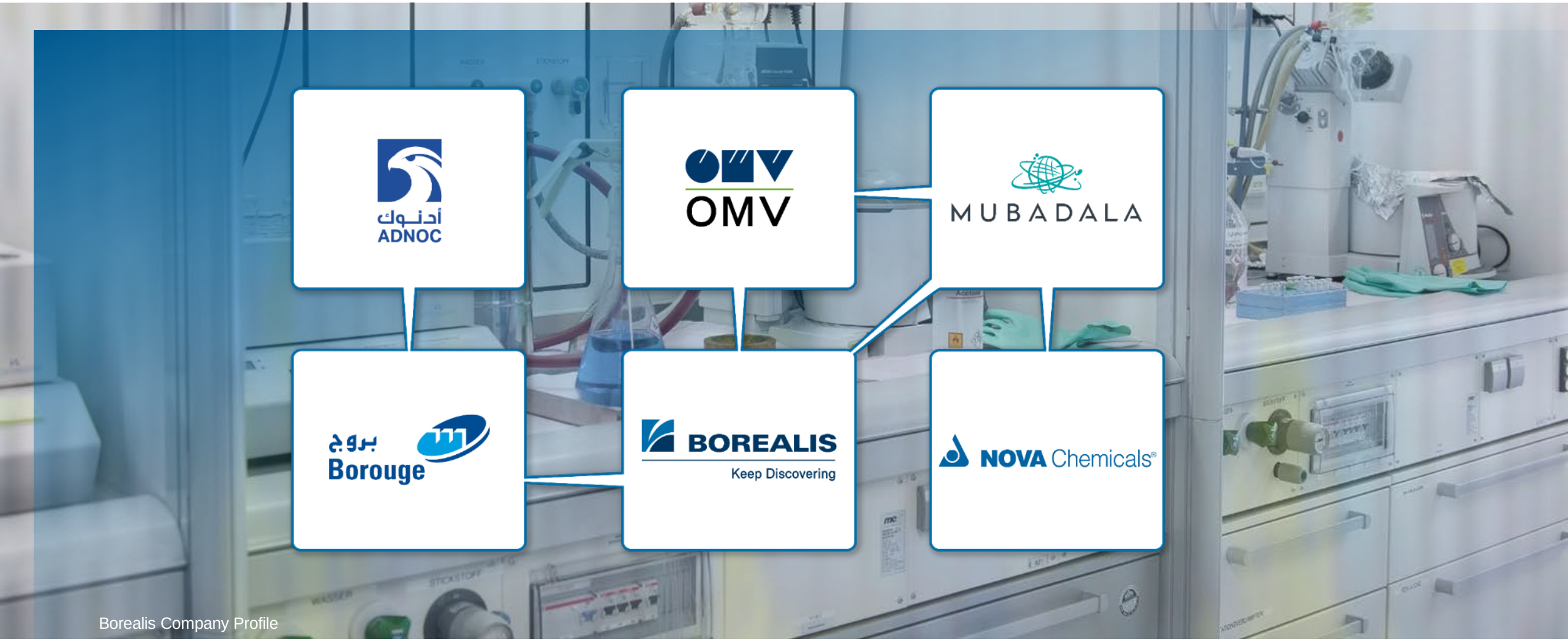
Circularity

Two **polyolefin recycling**
operations in Europe

Patents

120 priority patents
filed in 2019

A solid ownership structure provides a reliable foundation for the future

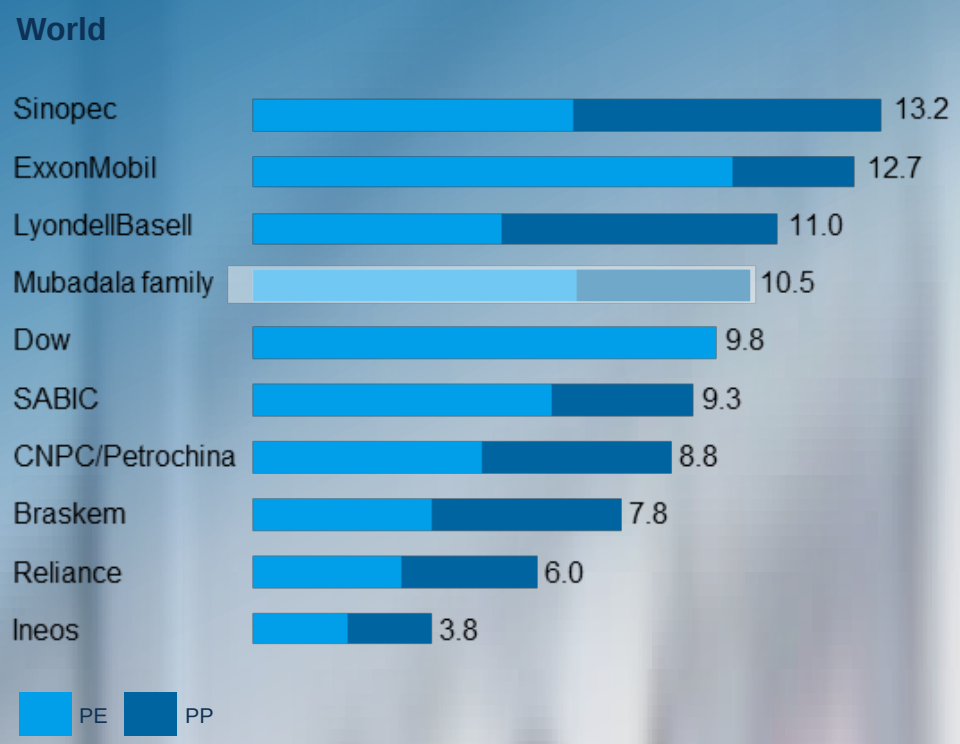


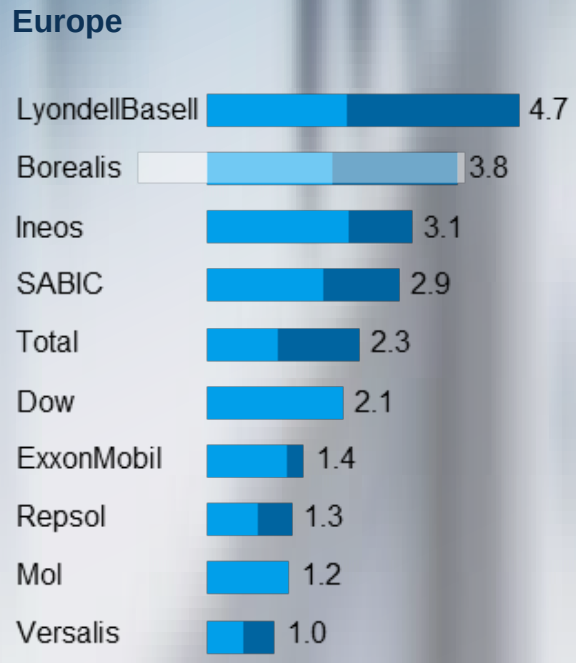
Borealis Company Profile

BOREALIS Borouge

Polyolefin Producers: Mubadala family & Borealis command top positions

Capacities year-end 2018 in MT, based on ownership share





Legend: Mubadala family refers to Borealis, Borouge & Nova
Source: Borealis and IHS

BOREALIS Borouge

Introducing Borealis

Setting the scene

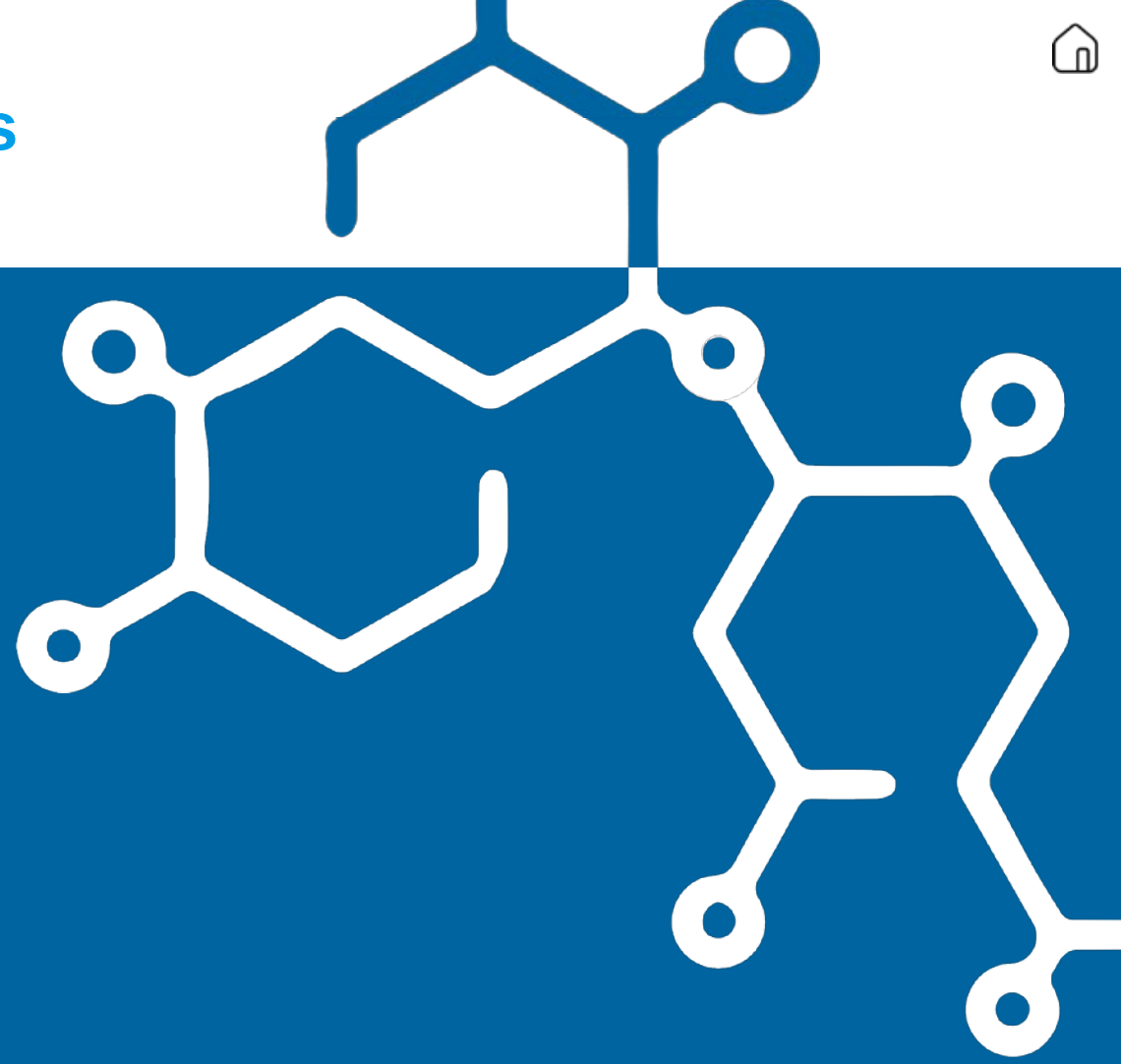
The Bormed Concept

What's new: products and services

The Healthcare dimension in Polymers

Often, the materials used in Healthcare applications are relatively standard. Only a few have specific Healthcare related properties i.e. for gamma irradiation.

What makes the difference for polymer producers supplying the Healthcare grade is their level of understanding of the industry they supply, added services and support.



The diversity of Healthcare applications (1/2)

Pharma Packaging

Pouch systems
PVC, PP, PE

Blister
PP, PVDC, PVC

IV Bottle
Glass, LDPE, PP

Caps & Closures
LD, HD, PP

Ampoules
Glass, LDPE,
PP, COC

Tubing

PVC, PP, PE,
compounds

The diversity of Healthcare applications (2/2)

Medical Devices

2,3 part syringes
(excl. gasket)
PP & HDPE

Meter Dose Inhalers
ABS, PC, PP

Prefilled syringes
PP, COC, glass

Dialysis filter housings
PP, PC

Insulin pens
PP, ABS,
PC, POM…

Diagnostics

PP, PS

The ‘missing’ Healthcare dimension in PO food approved grades

Typical changes associated with production of standard, food contact polymer grades…

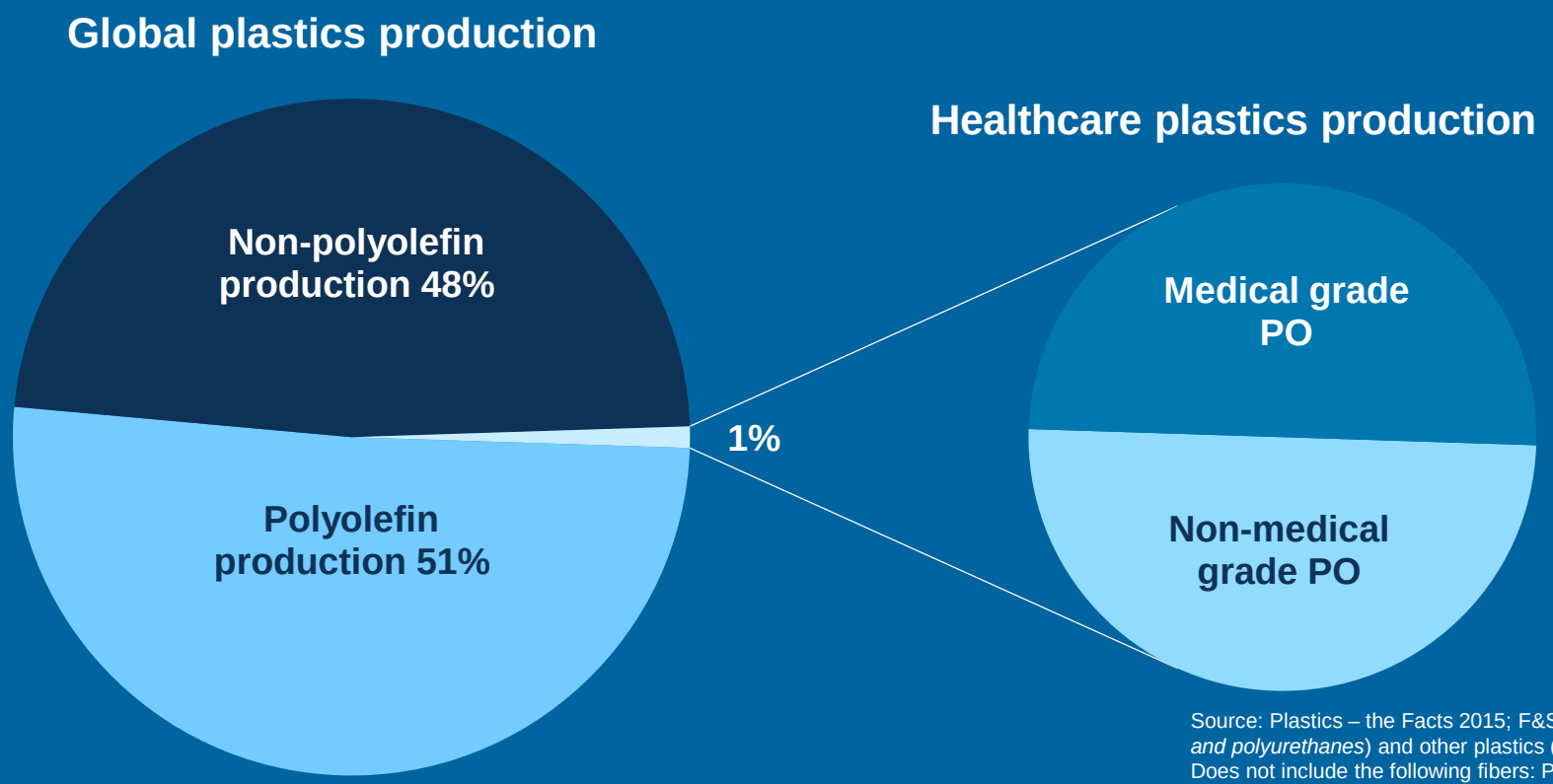
- Additive composition
- Production recipe (catalyst, process aid)
- Production technology
- Production location

…Are NOT typically notified

Ultimately this means that any Healthcare specific testing (compendial, stability, E&L….) of food contact polymers has **NO** relevance if the material is changed without notification **AFTER** the testing has been done. Patient safety can be compromised

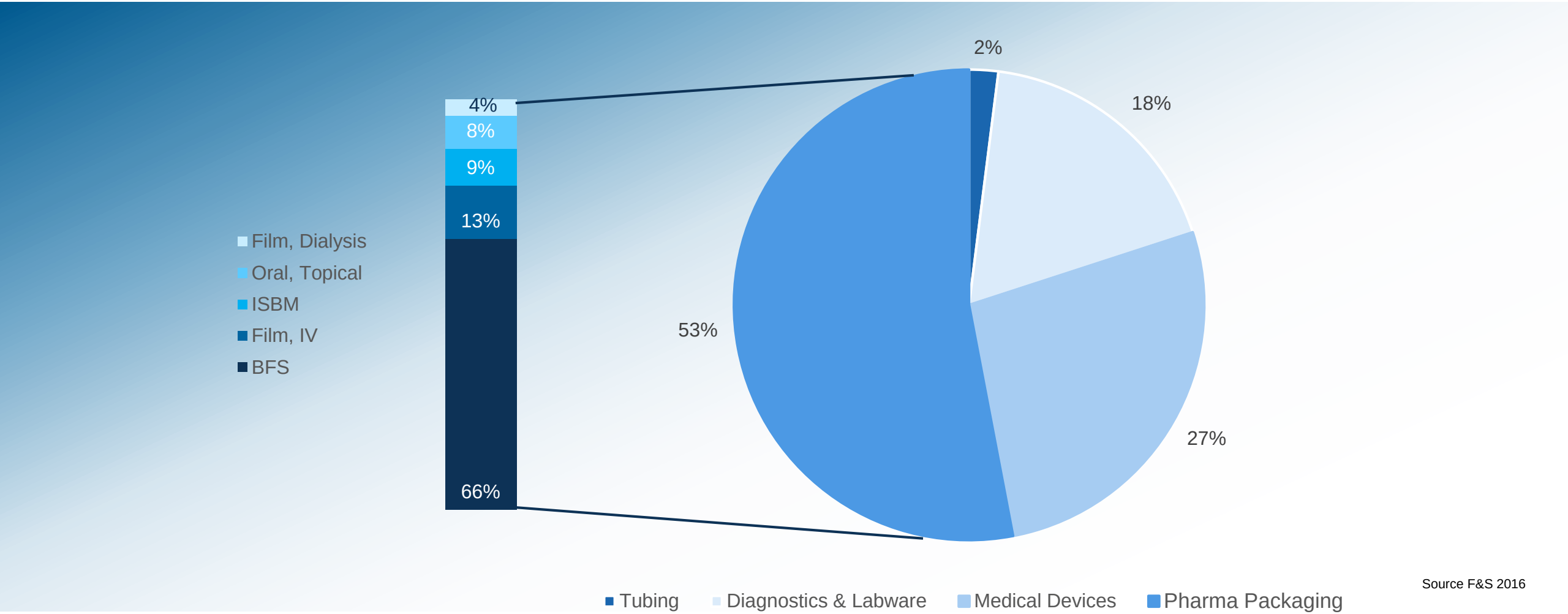
The share of Medical grades in polymer production is very small

Whilst the Healthcare space may have the highest quality requirements, it does NOT drive the raw material industry…



Source: Plastics – the Facts 2015; F&S 2016; includes plastics materials (*thermoplastics and polyurethanes*) and other plastics (*thermosets, adhesives, coatings and sealants*). Does not include the following fibers: PET-, PA-, PP- and polyacryl-fibers

More than 50% of medical grade polyolefins is a type of pharmaceutical packaging



Source F&S 2016

Introducing Borealis

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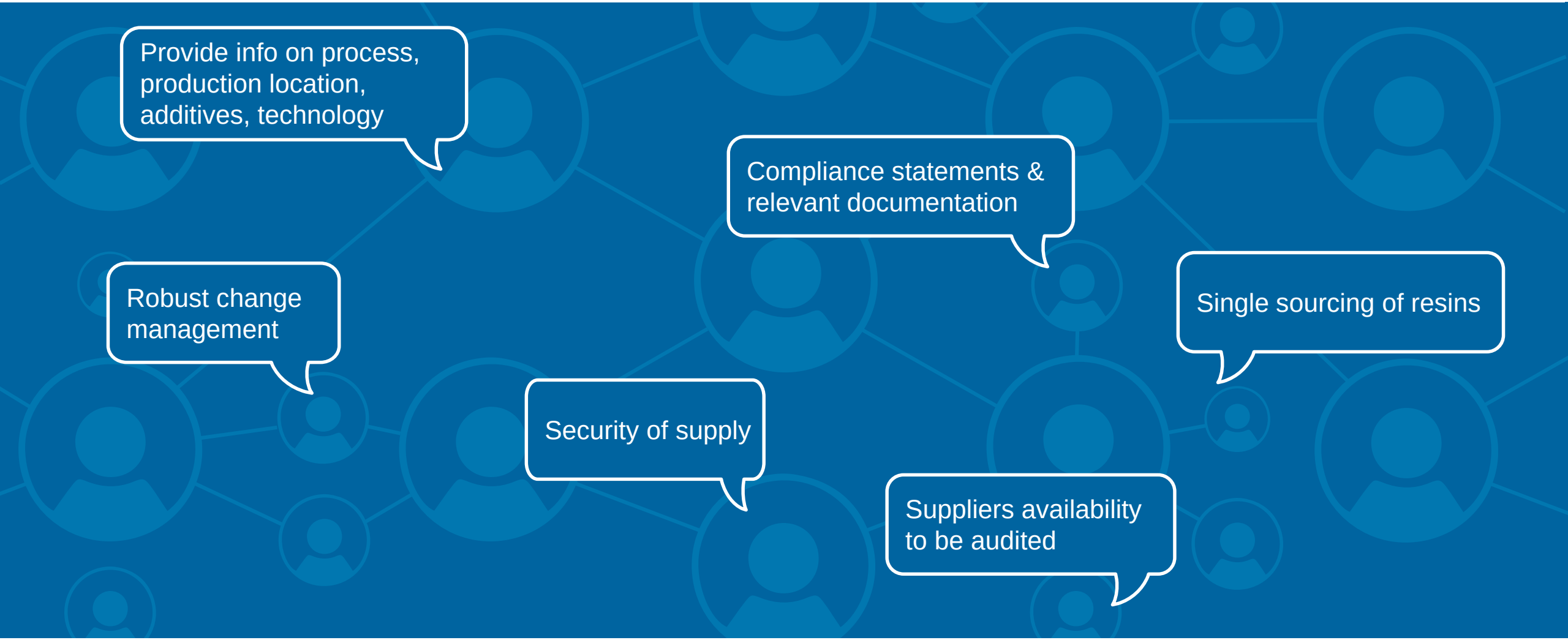
The Bormed Concept

What's new: products and services

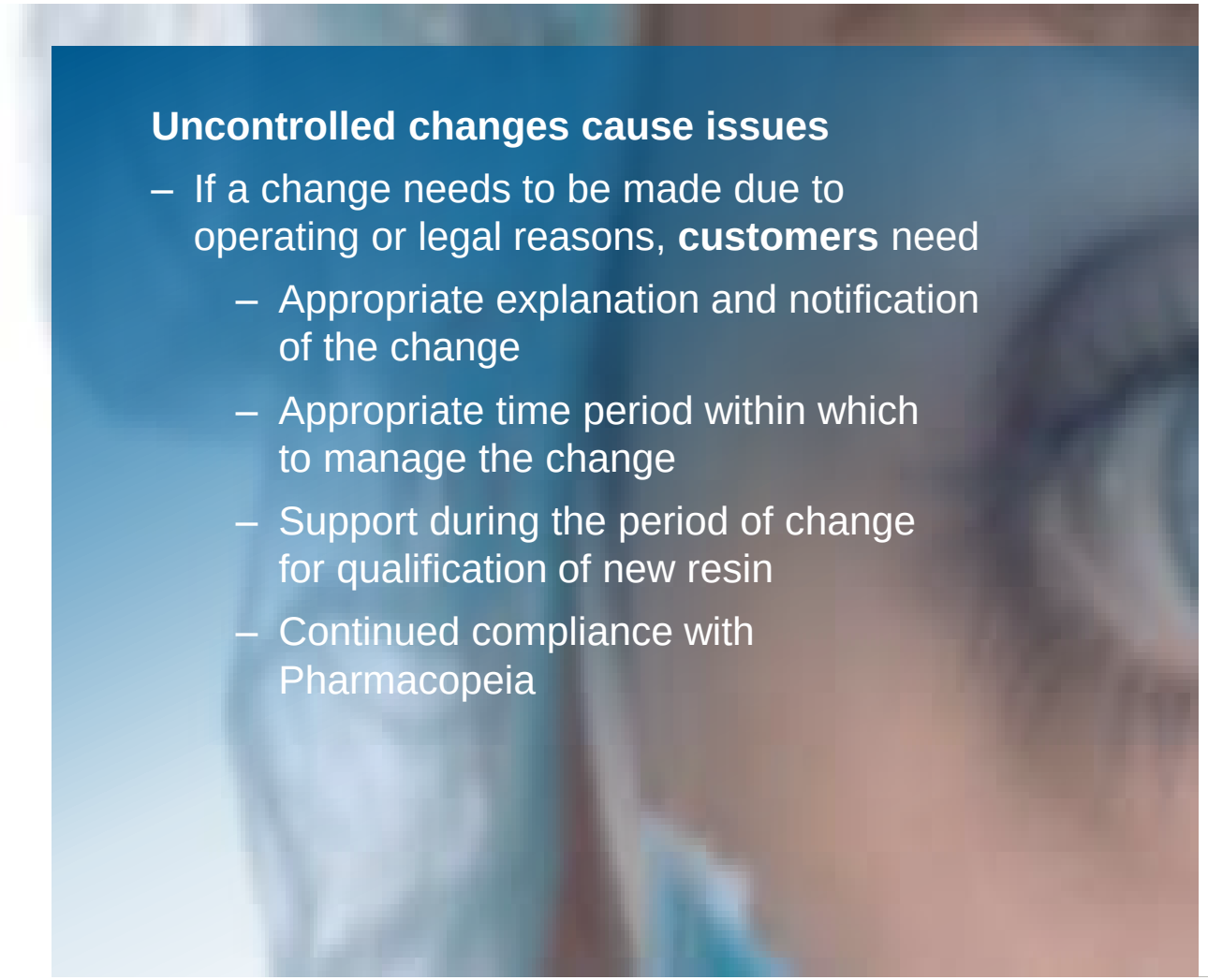
Conclusion & Summary

Some key challenges in the Healthcare Industry

What the market told us….a wish list



Customer ‘wish’ list – change management



Uncontrolled changes cause issues

- If a change needs to be made due to operating or legal reasons, **customers** need
  - Appropriate explanation and notification of the change
  - Appropriate time period within which to manage the change
  - Support during the period of change for qualification of new resin
  - Continued compliance with Pharmacopeia

How is this best secured?

- Through a change management procedure for polymers used in Healthcare applications to support **customers** control and de-risking process
- Supplier commitment fully integrated across the company portfolio as standard
- Branded portfolio of materials dedicated to the healthcare market

The Borealis approach to Healthcare

- Clear senior management commitment to Healthcare as a **strategic segment**
  - Evidenced through dedicated Healthcare Team
  - Healthcare fits with the company vision of being a leading provider of chemical and innovative plastics solutions that create value for society
- Dedicated product portfolio of branded resins: **Bormed™**
- Dedicated procedures
  - From raw materials to the delivery of **Bormed™** to customers door which reflect the changing requirements of the Healthcare Industry

Bormed: Because we care

Key focus area for Borealis: providing affordable and safe Healthcare

Through its portfolio of dedicated **Bormed™** products, Borealis and Borouge enable its customers to meet their need for high-quality, lightweight and aesthetic products

The **Bormed™** portfolio comprises of polyolefins for medical & diagnostic devices and pharmaceutical packaging with superior technical performance

Extended Healthcare Team… because we care!

Head of Marketing Advanced Products
Nina Ackermans

Mkt. Coordinator
Suhas Donthy
Suresh Babu

Business Development Manager, Healthcare
Paulo Cavacas

AMM
Niya Petzold

ADE
Emmanuel Boxus

ADE
Anja Gottschalk

ADE
Faruk Unluuysal

Head of Sales Advanced Products
John Webster

KCL & Germany
Markus Fuchs

FR, Iberia, Nordic
Charlotte Duperret

Benelux, DACH
Rob Strous

UK, Israel, Greece
Rob Nixon

Turkey, N. Africa
Ozan Aslan

Italy, SE
Eduardo Carraturo

NAM
Steven Whaley

Distribution & DE
Bastian Schenk

Product Management
Manfred Grünberger
Juliane Braun
Tom Blencowe
Thomas Papesch
Leon Welzen

Quality
Urs Pedrazza

Product Stewardship
Aino Haritonova

Legal
Ursula Nowak

Marketing Communication
Nathalie Benoit-Sommer

Supply & Demand Management
Joao Alves
Demand Response
Barbara Pammer
Demand Planner

Borouge
Saif Alderei
AMS

Bormed™ Concept: Dedicated service for the Healthcare Industry

COMMITMENT

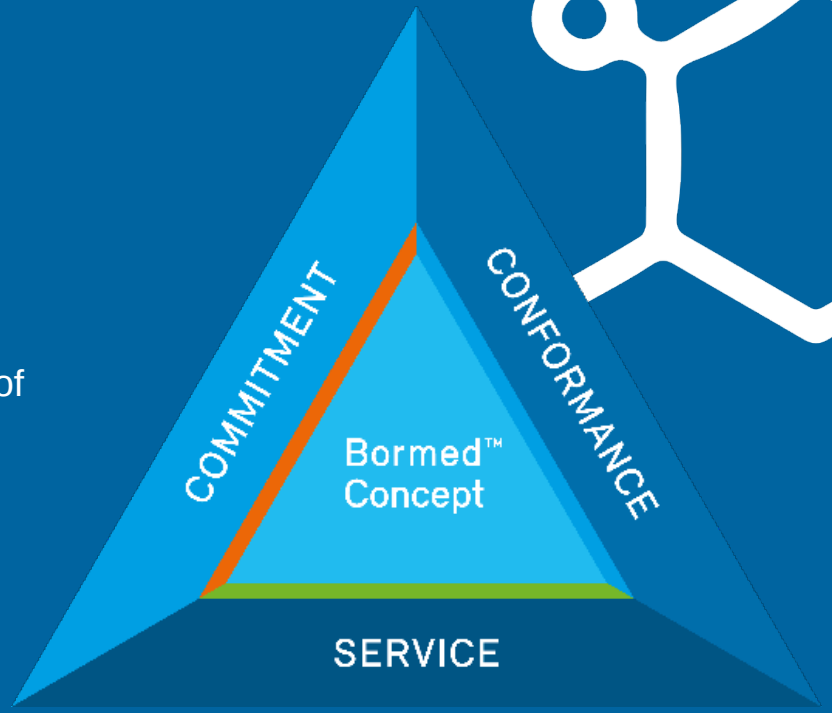
- Dedicated portfolio of branded PE & PP
- Continuity of supply regulated by Technical Delivery Specification
  - Product made available up to 5 years (2 years pre-notification and a last call volume combined with 3 year shelf life)
- Consistency of the product recipe via rigorous change control procedure
- The Bormed Directive (PO4047): operating instructions for the development, production, storage and delivery to the end customer of Bormed products

CONFORMANCE

- Pharmacopeia compliance
  - External Ph. Eur., USP (incl. 661.1) and ISO 10993 testing: analysis reports can be shared on request; DMF listing; following VDI guidelines on MGP

SERVICE

- Extractable profiles that can be shared on request
- Globally available dedicated team of experienced technical and regulatory specialists
- Innovation in products and services relevant for Healthcare industry



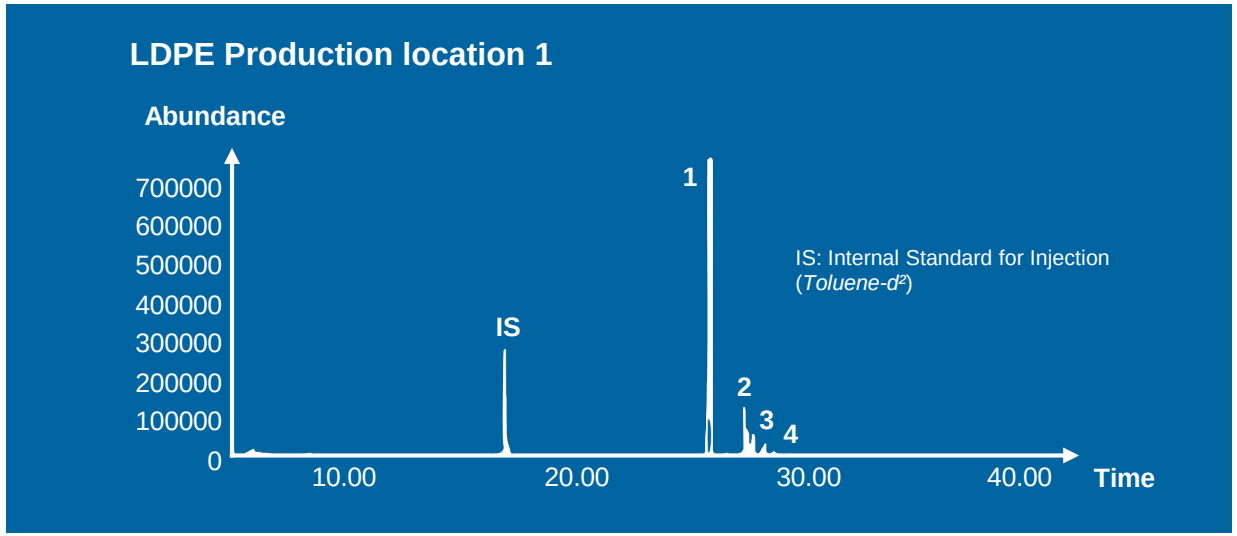
BOREALIS Borouge

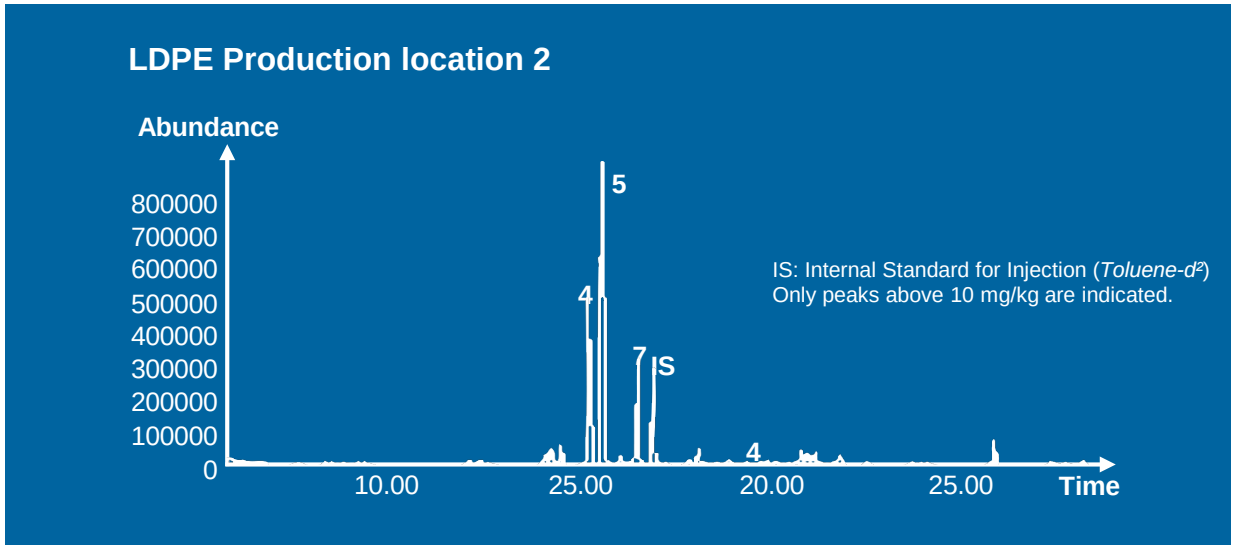
Technical Delivery Specification - Bormed de facto quality agreement

Once TDS signed, we agree to provide **proactive** notification on the following changes:

- Changes in the final grade composition based on CAS number
- Changes in physical properties of the grade as agreed in this document (*default – MFR for PP, MFR & Density for PE*)
- Change in either the production plant or technology
- Change in the grade name
- Change of the regulatory status of the grade: in case a change is made that affects the regulatory status of the grade

Going the extra mile: our extractable testing





- Extractives are generally LMW polymer, additives and species from processing e.g. degradation and side reaction products
- The profile of a few pellets will differ to a moulded and subsequently sterilised container. Adding colorant will change the profile further

Value for the customer

- Extractive data on resin can support informed decision making and validation at an early stage – time/money saving of customer's testing programme

Value for Borealis

- Being able to actually quantify on molecular level the effect changes could have

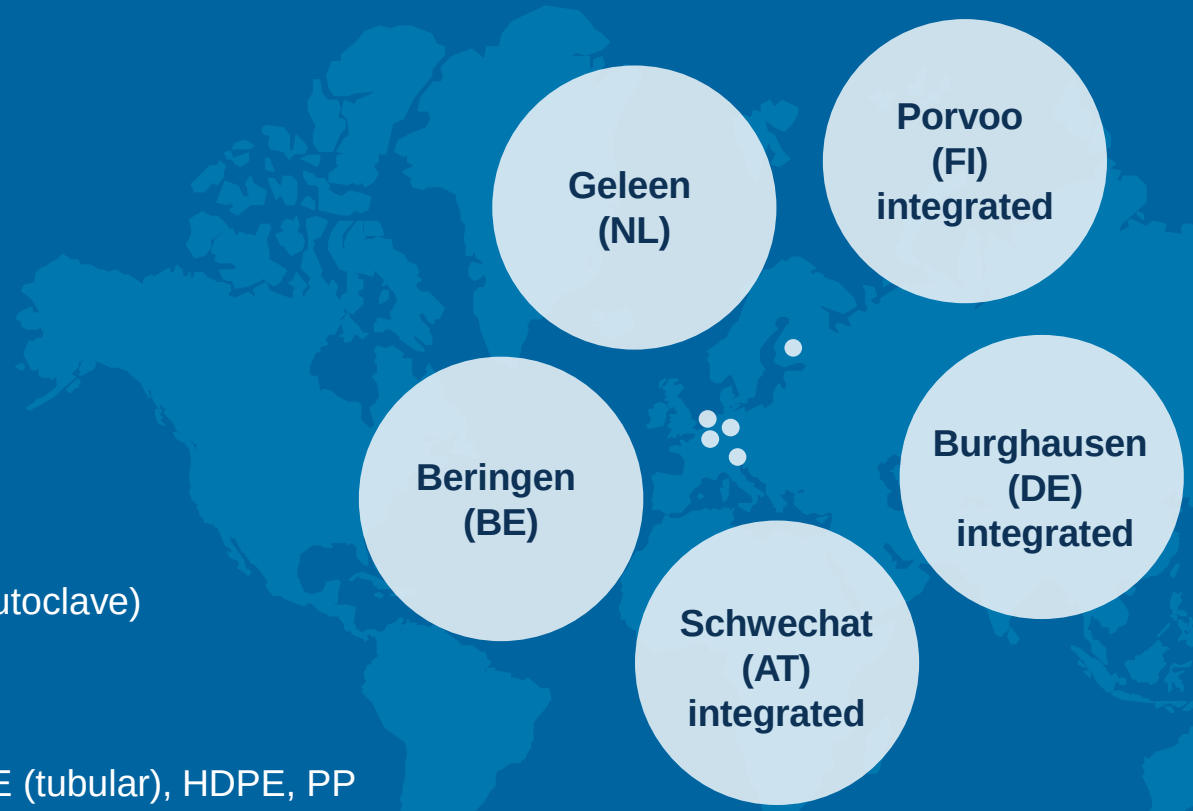
Extractable testing

- Testing programme determined in co-operation with Nelson Labs
- Programme consists of:
  - Headspace GC/MS on pellets: organic volatiles
  - Extraction with 3 solvents
    - GC/MS for semi-volatile organics
    - LC/MS for non-volatile organics
  - Identification of compounds present >5µg/ml
- Solvents are UPW, Ethanol and Hexane
  - Chosen to give the broadest possible dataset whilst still remaining relevant to majority of industry
- Extractable data can be shared under NDA along with composition disclosure (formulation) if request
- When change data provided, test side by side with control spike

Differentiated Borealis risk approach in Healthcare

- Borealis is committed to supporting the Healthcare industry; we therefore discuss **ALL** applications with the exception of permanent implants
- This practically means that higher risk applications (*class 2b & 3*) **are not** excluded from benefitting from the Bormed™ concept
- When the Borealis digital risk assessment form is completed fully and correctly, new, additional information is unlikely to be needed (*except for clarification*)
- Borealis does not require any additional liability insurance or declarations
- Borealis has internal targets to ensure that decisions are openly communicated within a reasonable timeframe: within 2 days for Class 1 or 2a and pharma packaging; up to 2 weeks for Class 2b or 3

Bormed™ production locations



- **Porvoo:** LDPE (autoclave)
- **Beringen:** PP
- **Burghausen:** PP
- **Schwechat:** LDPE (tubular), HDPE, PP
- **Geleen:** HDPE, Plastomers


Setting the scene
The Bormed Concept
What's new: products and services
Conclusion & Summary

Bormed™ BJ868MO
High flow, regulated heterophasic PP copolymer

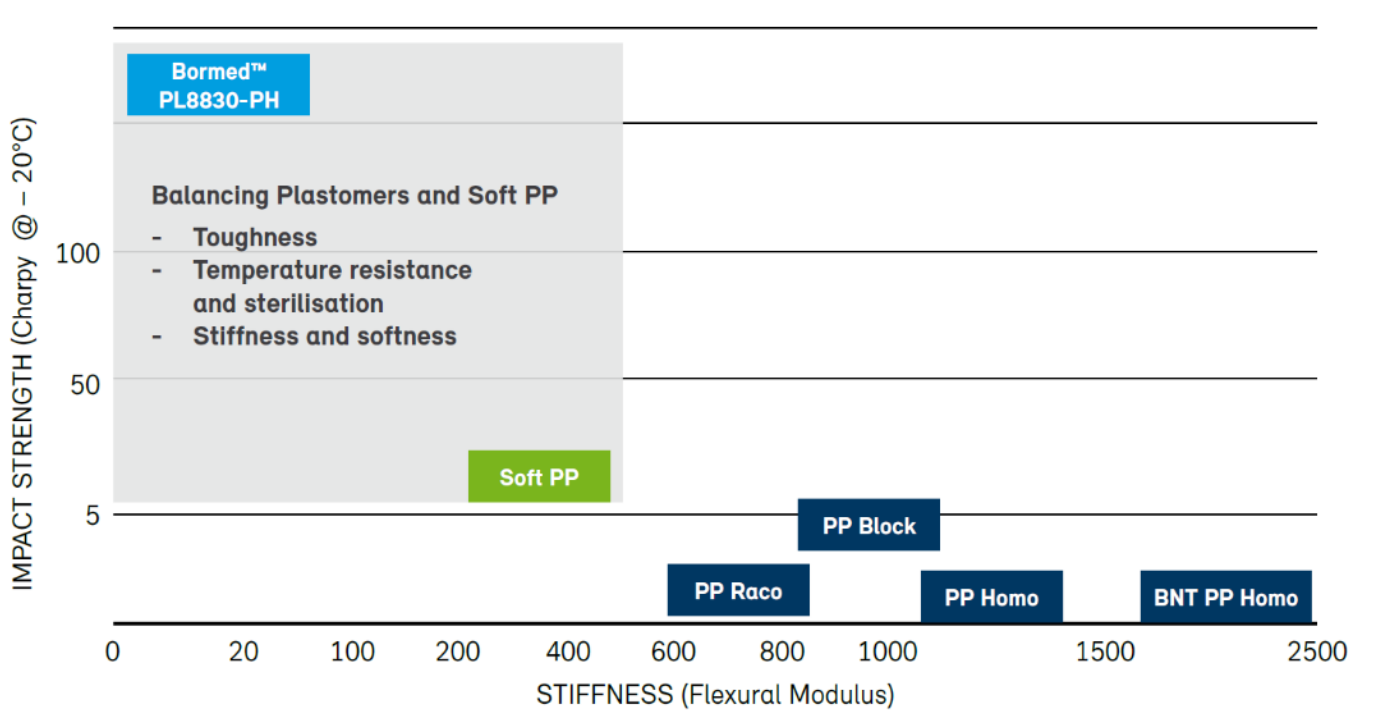
- **High flow, MFR 70 g/10 min**
  - Fast & easy mould filling; easy processing for complex shapes
- **Excellent impact resistance**
  - Minimum risk of breakage for the end user within a wide temperature range
  - Insurance of a good drop performance of final device in varying conditions (at refrigerator, deep freezer and sub-zero temp.)
- **Lower holding pressures, lower processing temperatures and faster cycle times**
  - Enhanced sustainability thanks to reduced energy consumption and CO2 emissions

©Premix group

Typical applications
Pipette tips, PCR* plates, multi-well titre plates, high cavity applications for medical/diagnostic devices and medical labware

Bormed™ PL8830-PH & Bormed ™ Soft PP
Enlarging the PO performance envelope in Pharma packaging

IV POUCHES
Bormed PL8830-PH & Bormed Soft PP



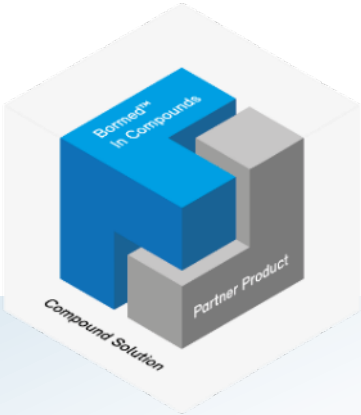
Key benefits

- Allow significant reduction of impact modifiers in film formulation
- Excellent balance between high toughness at low temperature and good transparency after steam sterilisation
- Secured processing window for steam sterilisation at 121ºC; offers opportunities as blending / compounding component

BOREALIS Borouge

For the complete Bormed product portfolio click here

Bormed™ InCompounds



- By partnering with trusted and recognised healthcare compounders, we extend the Bormed reach to compound solutions. In doing so we ensure that every end-customer can get the **requested tailor-made solution based on Bormed**
- The combination of a **very broad polyolefin product offering within the Bormed portfolio**, ranging from stiff PP homopolymers to soft PP, LDPE, HDPE and plastomers, and a **high customisation potential** at our partner compounders offers an unprecedented enlarged array of solutions to their needs
- We provide consistent and high quality materials with a strong focus on regulatory compliance, dedicated change control and security of supply. These are the criteria we also base our selection of partners on
- Using Bormed in all components, **can enable customers to manage or reduce the number of variables in their final products** that are subject to regulatory approval and can facilitate change management efforts
- Thus, we offer **“peace of mind”** in the moment of selecting raw materials for healthcare packaging or devices, being those a Bormed virgin resin solution or a partnering compound based on Bormed

Because we care – Bormed™ InCompounds

Bormed InCompounds - selection criteria

Partners are carefully selected to stick to our promise of highest product quality

Being a cross promotion opportunity open to different compounders it is key to safeguard that only trustworthy companies can be referenced

Partner selection criteria

- To have a healthcare product brand
- Dedicated organisation, e.g. demonstrated through a healthcare marketing manager/business development manager
- ISO13485-2016
- Open for customer audits
- Internal change control procedure available
- Dedicated HC team consisting of application and regulatory experts
- Document management capabilities to meet compliance needs

Our current partners

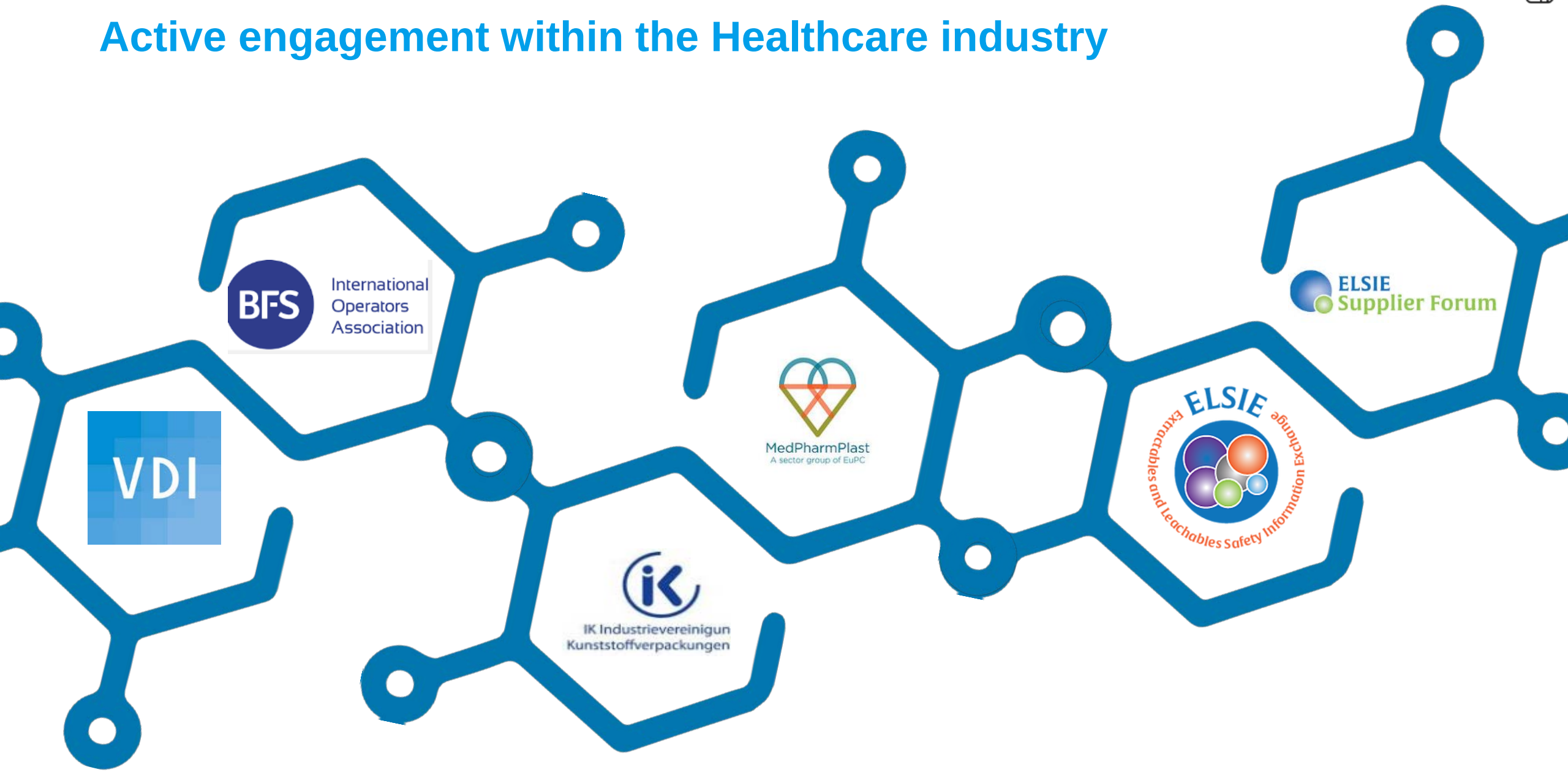
WITTENBURG GROUP

CLARIANT

MELITEK

BOREALIS Borouge

Active engagement within the Healthcare industry



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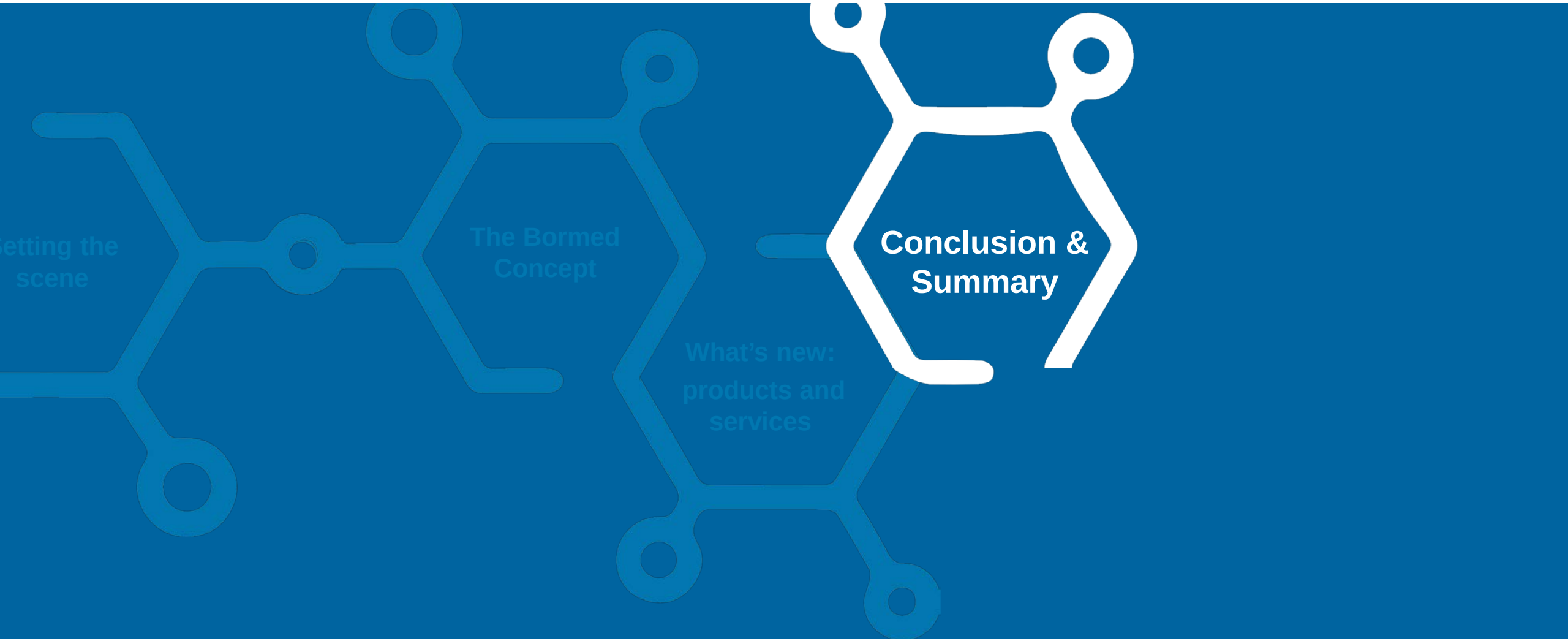
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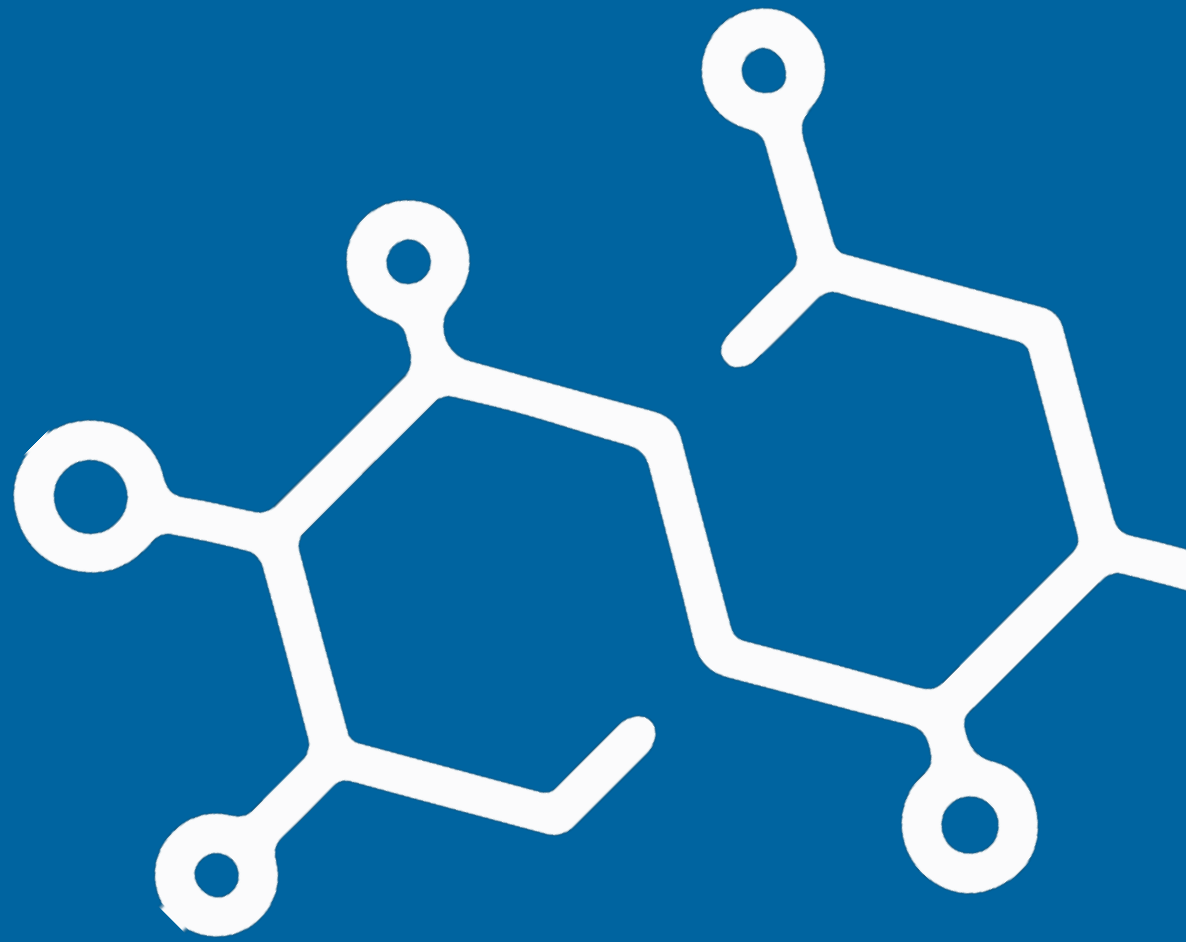
Conclusions

- Healthcare specific testing, whether extractives or compendial testing, only makes sense if the material production is **controlled**
  - Remember: Ph.Eur is only tested on a small number of granules
- Therefore, resin producers can support the industry
  - By minimising variance through dedicated materials for Healthcare and providing non-change commitments - **Bormed™**
  - Engaging with customers to help them understand polymer chemistry
  - Developing and enforcing a change management procedure for polymers used in Healthcare applications to support control and de-risking process

The right choice of service provider is as important as the right material



Click here to download our brochure 'Bormed™ solutions for healthcare moulding and film applications'

Thank you