



**xellia**  
PHARMACEUTICALS

# **Xellia Pharmaceuticals**

## **Corporate presentation**

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# Our purpose










## Goal

Xellia's goal is to provide anti-infective solutions against multi-drug resistant micro-organisms

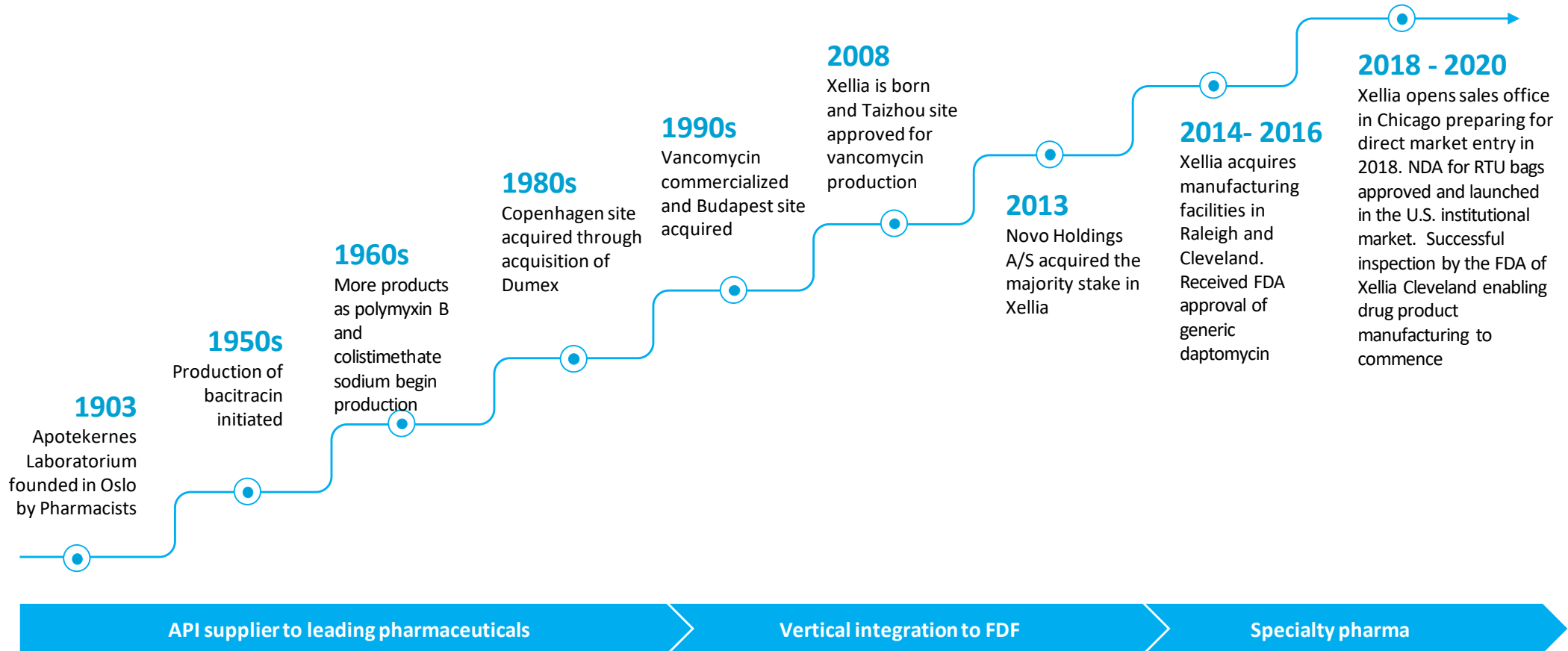
## Purpose

Xellia's purpose is to save and enhance lives by leading the fight against infections

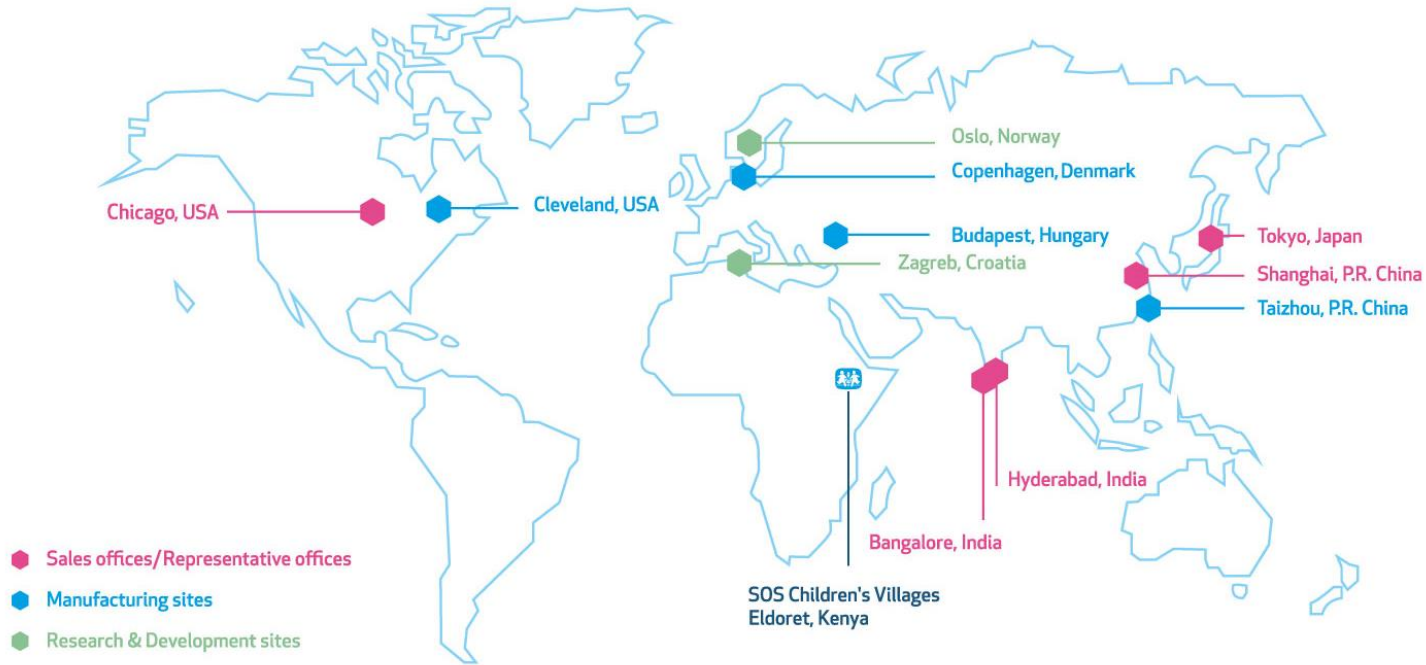
# Xellia in numbers

	117	Years of history in pharmaceutical specifically fermented and semi-synthetic anti-infective production
	500	Plus customers in over 70 countries, own direct Sales in US Hospital Channel
	21	Molecules in the portfolio which form core of modern day hospital treatment
	90+	Marketing Authorizations, 17 ANDAs and 3 NDAs
	4	Manufacturing sites around the globe with an impeccable compliance record
	12	Locations around the globe engaged in production, R&D and sales
	1700+	Employees across functions around the globe

# Our heritage



# Our sites



Our vertical integration strategy from research and development through distribution sets us apart as a unique partner to supply our customers



Oslo



Zagreb



Budapest



Copenhagen



Taizhou

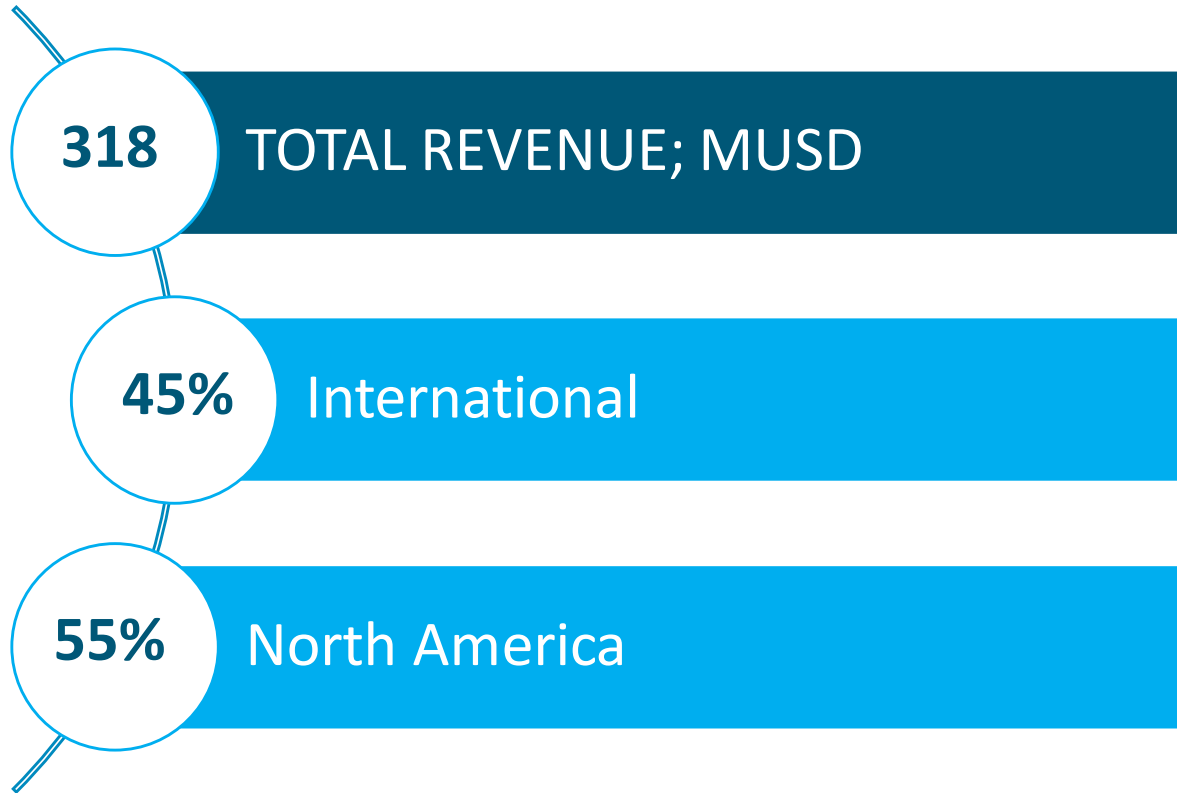


Cleveland



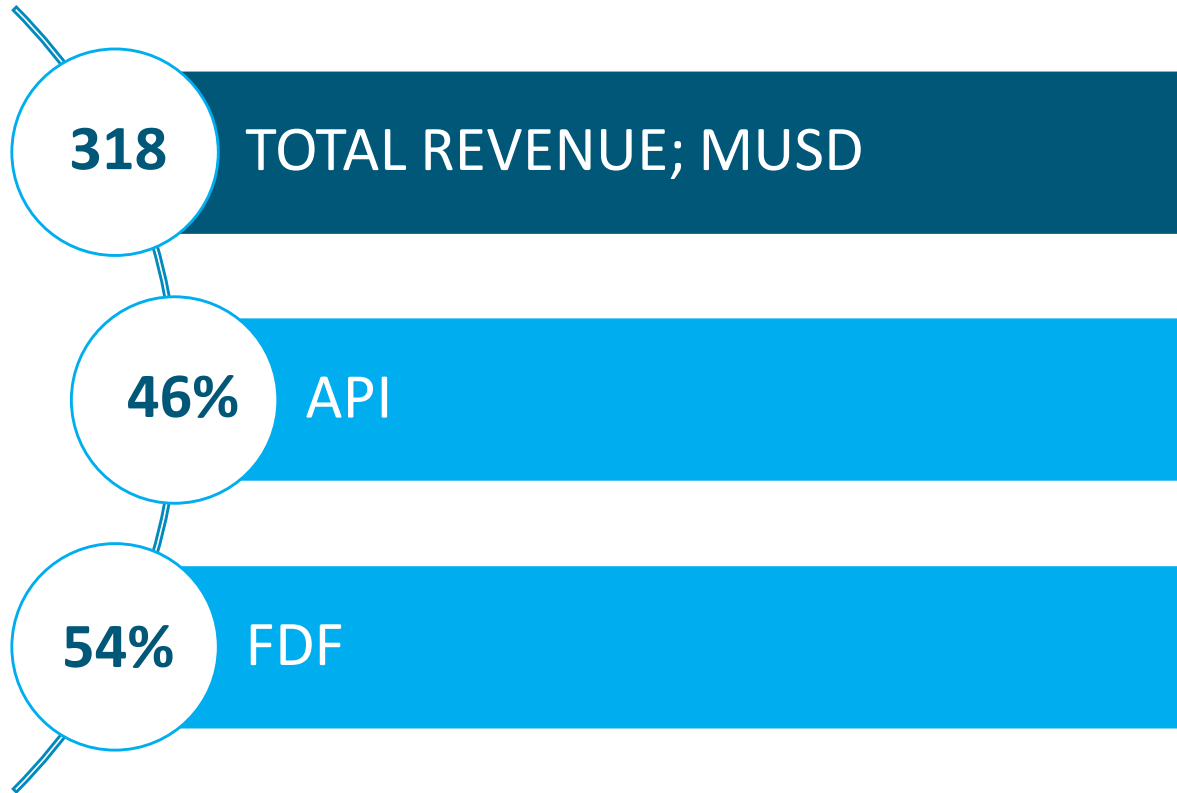
Copenhagen

# Our sales – Business unit split



2020

# Our sales – Product portfolio split



2020



# Our capabilities



- 1 150+ scientists with strong expertise in fermentation and semi synthetic products
- 2 Comprehensive portfolio of non  $\beta$ -lactams anti-infective that form core of hospital treatment
- 3 Innovative solutions to aid healthcare professional reduce error, contamination and save time
- 4 5 state of the art mfg. plants in US, EU and Asia
- 5 Strong focus on quality evident from 20+ year of compliance and regulatory/ customer audit record
- 6 Vertically integrated in all major products with sufficient redundancies ensuring continuous supply
- 7 500+ B2B customers in over 70 countries with long standing business relationship and US B2i entry in 2018

# Research and development



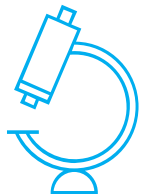
## Scientists

150 scientists in Oslo and Zagreb supported by state of the art laboratories spanning 5,200 square meters



## API expertise

Highly skilled in development and production of fermentation and semi-synthetic small molecules based products



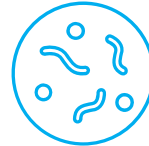
## Vertical integration

Develop vertically integrated products, from API manufacturing processes to finished formulations



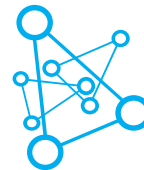
## Therapeutic area focus

Anti-infectives including both anti-bacterial and anti-fungal compounds. Other critical care products for the hospital market



## Formulation expertise

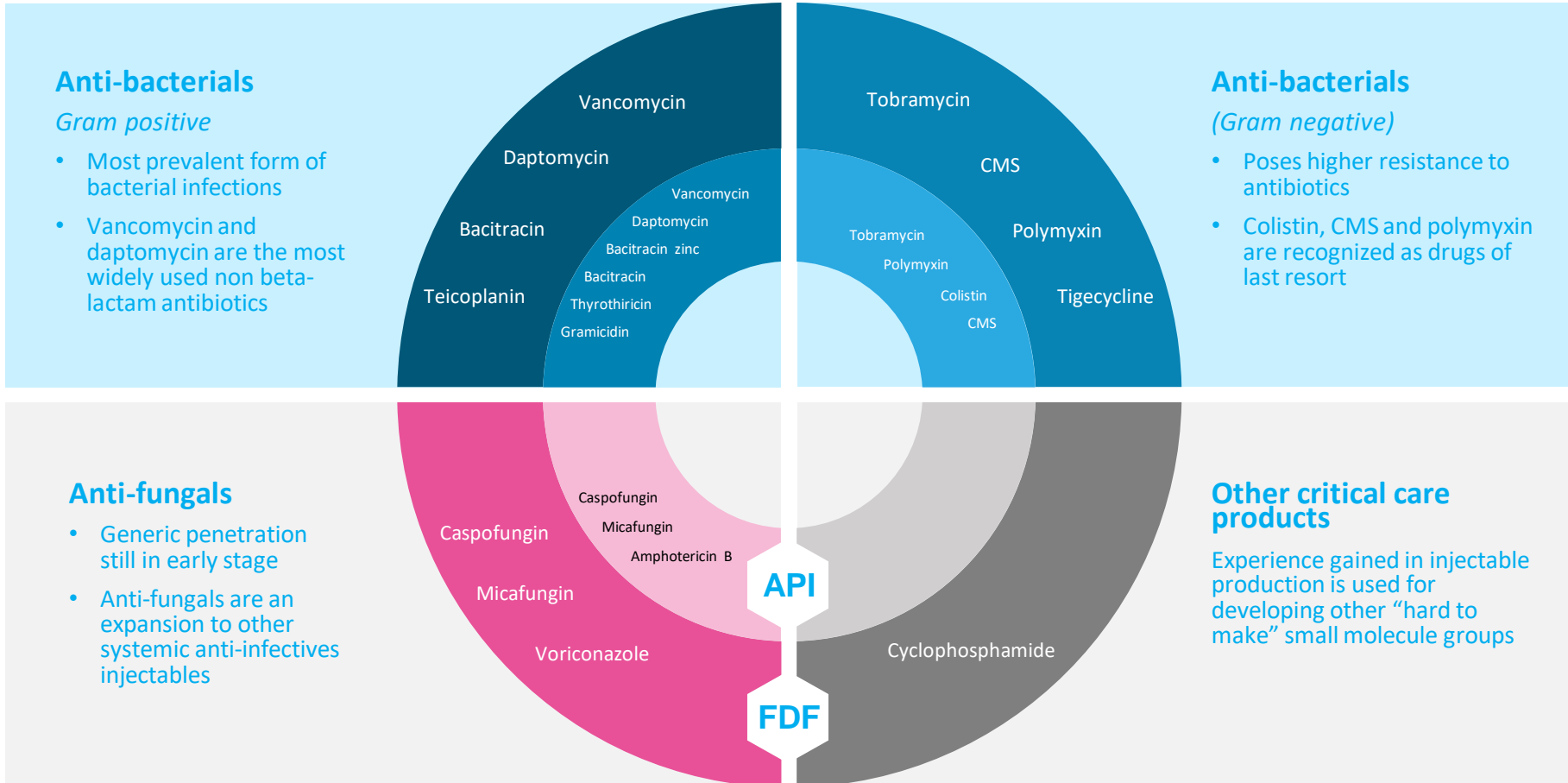
Focused on “difficult-to-develop” finished dose formulations with an intrinsic competitive advantage and benefit for healthcare professionals



## Formulation focus

Generic injectables, value added specialty injectables and new therapeutic entities

# Our product portfolio



# Manufacturing – API manufacturing sites

Technology/ Capability	Product/ Expertise
<ul style="list-style-type: none"> <li>• Fermentation</li> <li>• Purification</li> <li>• Bulk lyophilization</li> <li>• Sterile and non sterile grade (ST and NST)</li> </ul>	<ul style="list-style-type: none"> <li>• All small molecule products requiring non contained manufacturing</li> <li>• Final handling expertise including all common drying technologies (filter-, vacuum-, freeze-, and spray-drying)</li> </ul>



Site specific information	Products	<ul style="list-style-type: none"> <li>• Amphotericin B</li> <li>• CMS, colistin</li> <li>• Polymyxin B</li> <li>• Tobramycin</li> <li>• Bacitracin ST</li> <li>• Bacitracin zinc ST</li> <li>• Vancomycin</li> </ul>	<ul style="list-style-type: none"> <li>• Daptomycin</li> <li>• Vancomycin</li> <li>• Gramicidin</li> <li>• Tyrothricin</li> </ul>	<ul style="list-style-type: none"> <li>• Vancomycin</li> <li>• Bacitracin</li> <li>• Bacitracin zinc</li> </ul>
	Inspections / approvals	<ul style="list-style-type: none"> <li>• FDA 2018</li> <li>• ISO 14001</li> <li>• OHSAS 18001</li> <li>• DMA 2017</li> </ul>	<ul style="list-style-type: none"> <li>• FDA 2015</li> <li>• ISO 14001</li> <li>• OHSAS 18001</li> <li>• NIH 2014</li> </ul>	<ul style="list-style-type: none"> <li>• FDA 2018</li> <li>• ISO 14001</li> <li>• OHSAS 18001</li> </ul>

# Manufacturing – FDF manufacturing sites

Technology/ Capability	Product/ Expertise
<ul style="list-style-type: none"> <li>• Lyophilization in vials</li> <li>• Dry powder in vials</li> <li>• Aseptic liquid filling</li> <li>• Aseptically Ready-to-use (RTU) bags in execution</li> </ul>	<ul style="list-style-type: none"> <li>• Bulk and vial lyophilized products</li> <li>• Aseptic dry powder and liquid fill vials</li> <li>• Fill-finish capabilities for most vial sizes</li> </ul>



Site specific information	Products	Copenhagen	Cleveland
	Inspections / Approvals	<ul style="list-style-type: none"> <li>• Vancomycin</li> <li>• CMS</li> <li>• Bacitracin (planned)</li> <li>• Polymyxin (planned)</li> </ul>	<ul style="list-style-type: none"> <li>• Vancomycin manufacturing expected to commence in 2020 with planned expansion into other molecules and dosage forms</li> </ul>

## Xellia is a global leader . . .

Xellia-owned API source

Bacitracin vials

Colistimethate sodium lyophilized vials

Daptomycin vials

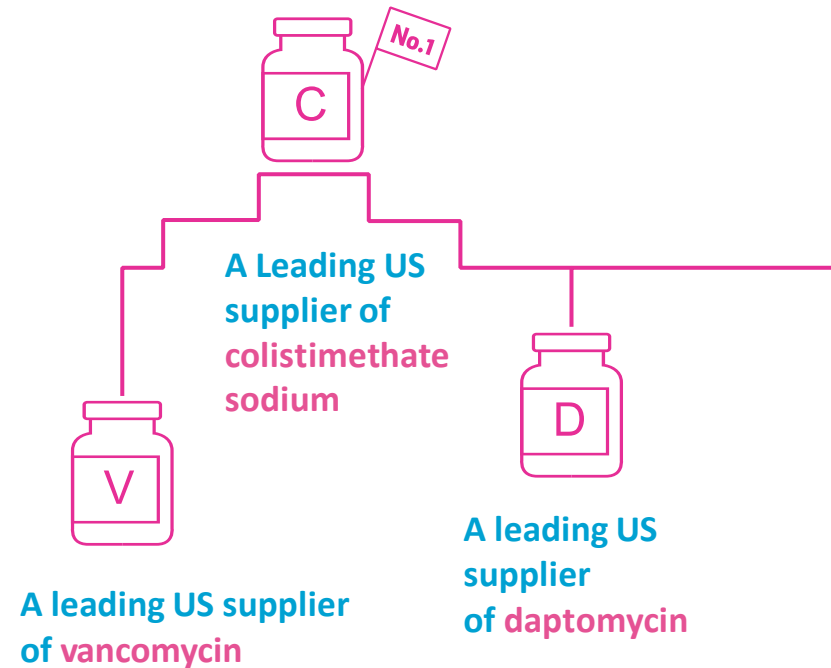
Polymyxin B sulfate vials

Tobramycin sulfate vials

Vancomycin hydrochloride vials

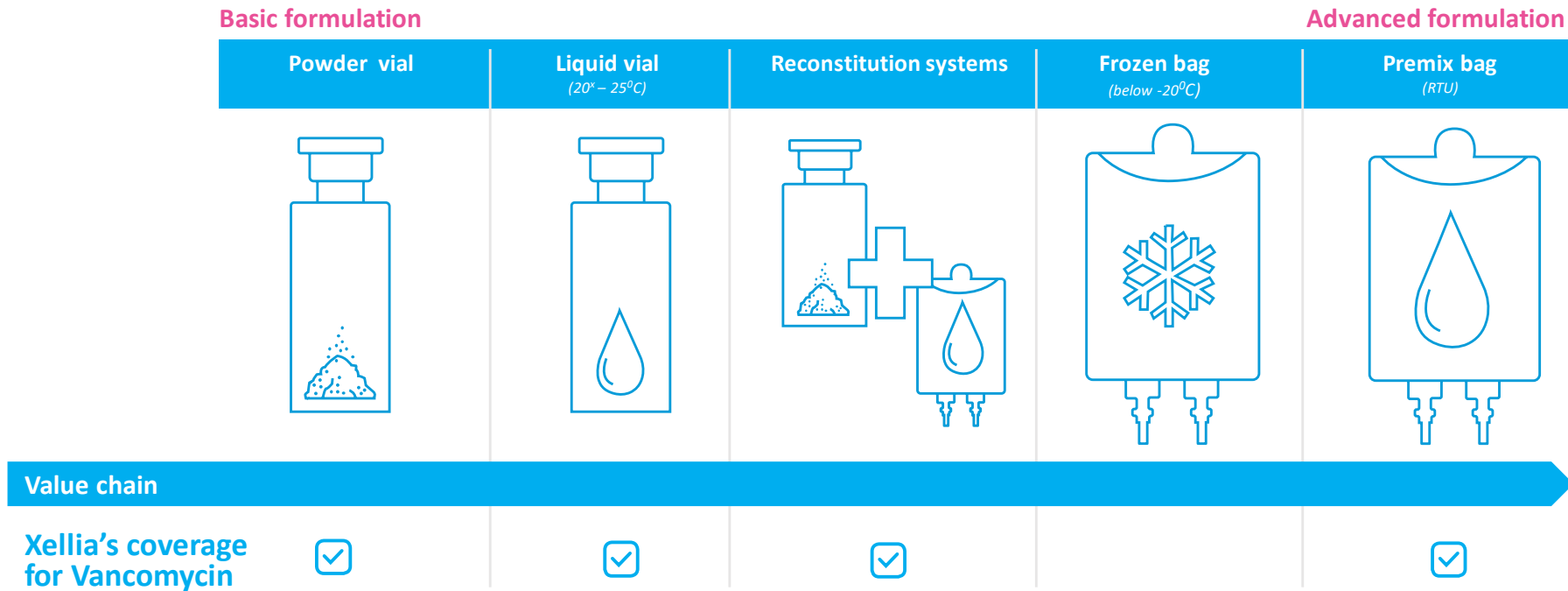
Xellia produces FDFs for multiple major pharma companies

## . . . in sterile injectables

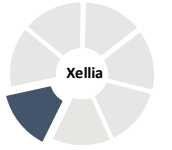


# Parenteral delivery solutions – our future

Focus is to offer a complete range from standard formulations to advanced delivery systems based on proprietary technologies



# Quality and compliance



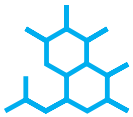
## Regulatory audits

All regulatory inspections passed without any critical observations during last 5 years



## Quality management review

Quality management review conducted every quarter by senior management



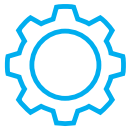
## Customer audits

218 successful customer audits during last 5 years



## Patient and product safety

Excellent track record – no product recalls



## Continuous improvement

Quality systems, release processes, organization



## Full compliance

No warning letters in the past 20 years



# Supply chain – Vertical integration

## Vancomycin redundant capacity, multiple sites, complete product offering

### Vancomycin

- 3 API manufacturing sites (Copenhagen, Budapest, Taizhou)
- 3 FDF manufacturing sites (Copenhagen, Cleveland, CMO)
- Multiple dosage forms (Iyo, liquid, RTU bags)

Our vertical integration strategy from research and development through distribution sets us apart as a unique partner to supply our customers

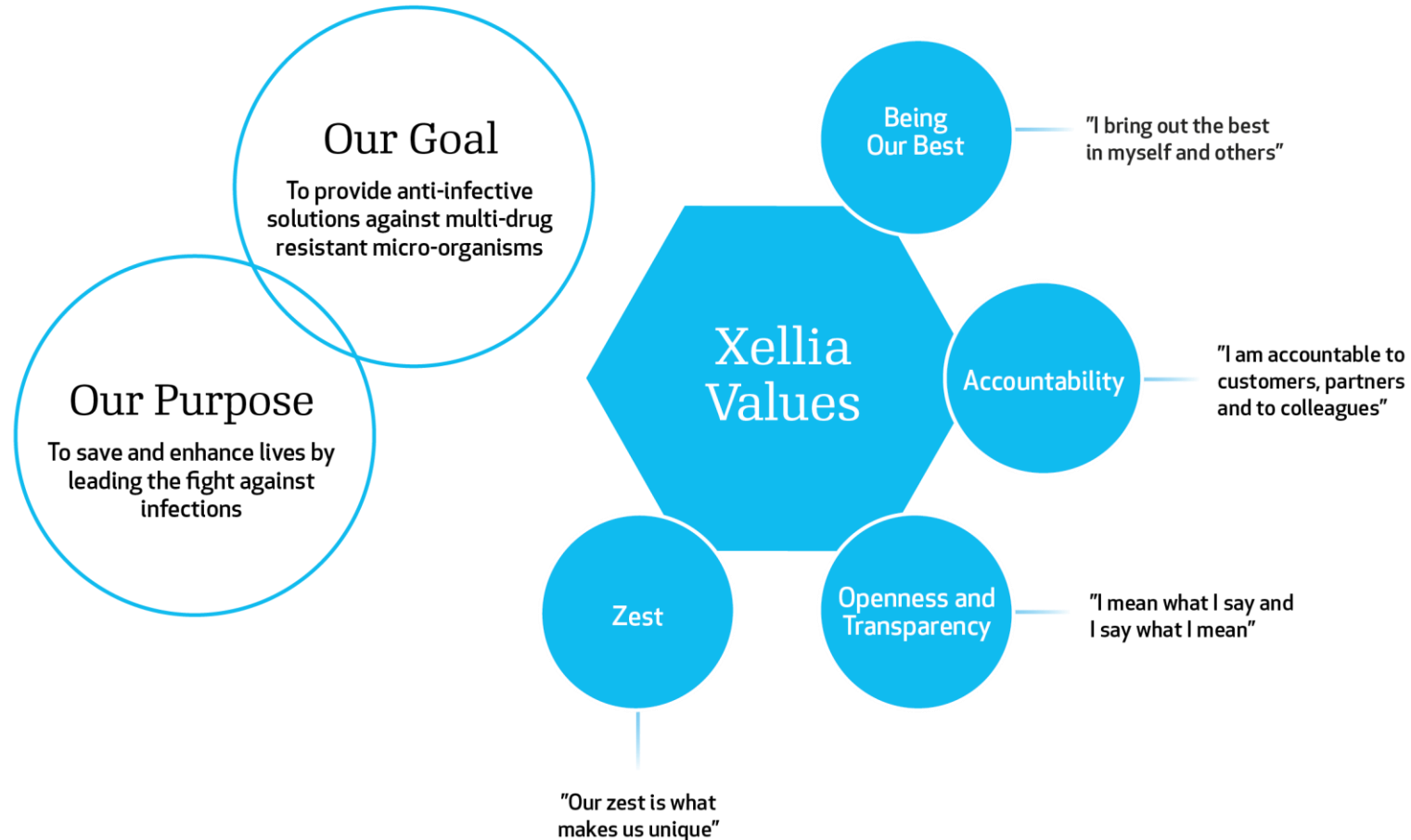
# Supply chain – Vertical integration

## Selected example of other products with multiple sites and targeted product offering

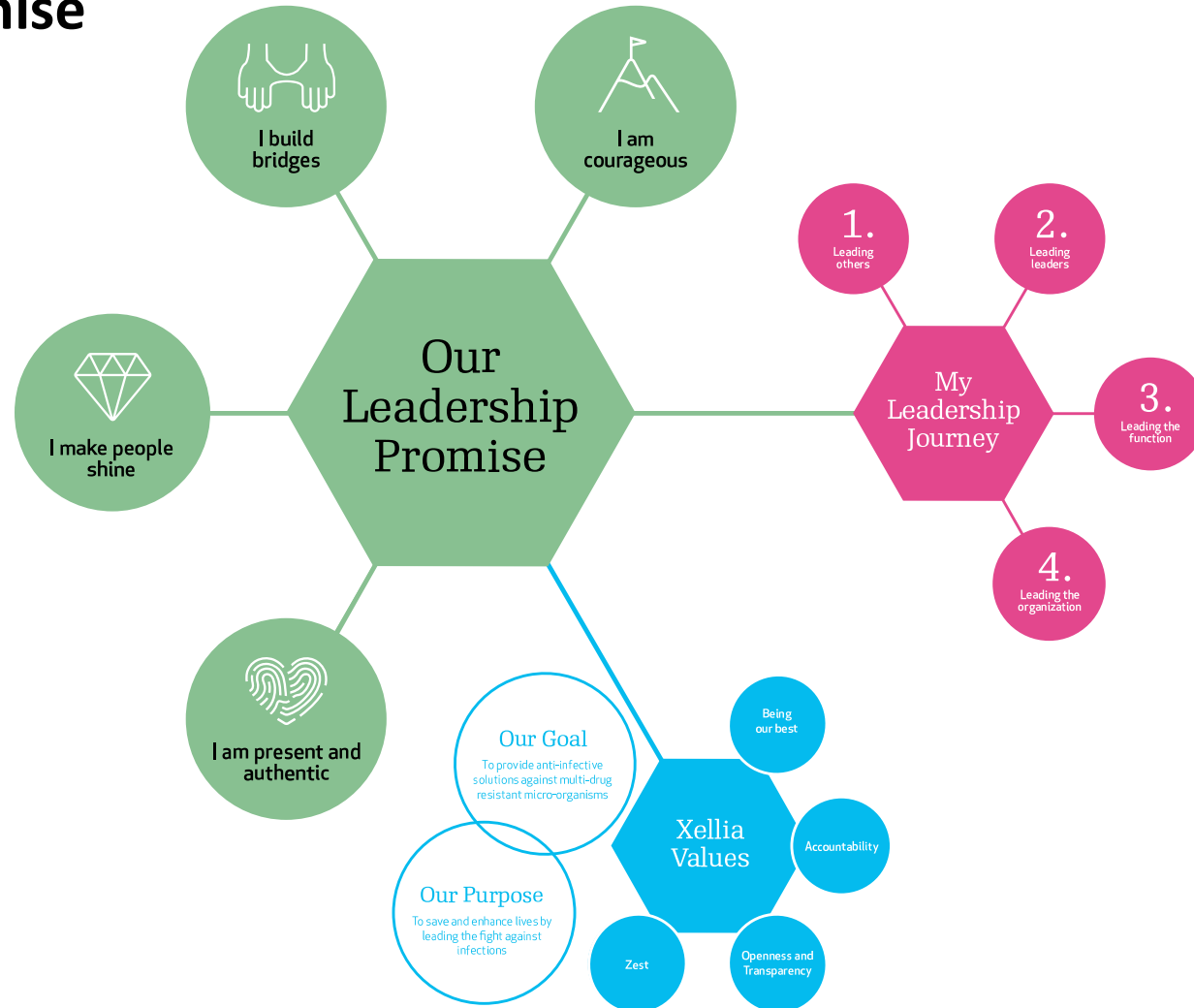
<b>Daptomycin</b>	<ul style="list-style-type: none"><li>• 2 API Manufacturing sites (Budapest, CMO)</li><li>• 2 FDF manufacturing sites (Copenhagen, CMO)</li><li>• Multiple dosage forms in development</li></ul>
<b>CMS</b>	<ul style="list-style-type: none"><li>• 1 API and FDF manufacturing site (Copenhagen)</li><li>• Multiple dosage forms (dry fill, lyo, liquid, inhalation)</li></ul>
<b>Bacitracin</b>	<ul style="list-style-type: none"><li>• 1 API manufacturing site (Taizhou)</li><li>• 2 FDF manufacturing sites (Copenhagen, CMO)</li></ul>

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# Our values



# Our leadership promise



# Our corporate and social responsibility



2015-2017

- In January 2015, Xellia Pharmaceuticals announced its three year partnership (2015-2017) with the Danish branch of SOS Children's Villages Denmark to fully sponsor the SOS Medical Center in Eldoret, Kenya
- In 2018, Xellia Pharmaceuticals' funded the expansion of the Medical Center with the establishment of a new Maternity Wing
- Today, the Medical Center is self-sufficient

2018-2020

- 3 year partnership
- In January 2018, Xellia began the funding of the operations of the SOS Family Strengthening Programs (FSP) in Eldoret, Kenya through the SOS Social Center
- The Social Center supports families and children through ensuring food, clothing, shelter and education
- FSP coordinates healthcare related outreach campaigns in joint cooperation with the SOS Medical Center

# Our board of directors



**Steen Riisgaard**

Steen is the Chairman of the BoD. He is former President and CEO of Denmark-based biotech company Novozymes A/S. He has also held senior level positions at Novo Nordisk A/S and Novo Industri A/S.



**Andreas Rummelt**

Andreas is a Partner and CEO of InterPharmaLink AG, Basle, Switzerland. His international career spans over twenty years in executive management positions at Novartis.



**Benny D. Loft**

Benny is former EVP and CFO at Novozymes A/S. Since Novozymes' launch in 2000, he has also worked on acquisitions and negotiations and played an active role in steering groups for numerous corporate functions including ethics, sustainability and business development.



**Per Valstorp**

Per Valstorp has a long track record attained from senior executive positions held at Novo Nordisk A/S within Pharma Operation Management, Quality, Regulatory Affairs and Medical Devices.



**Julie McHugh**

Julie McHugh has a track record that spans 27 years in the biopharma industry. Most recently, she was the COO at Endo Health Solutions, Inc., with responsibilities for both the specialty and generic pharmaceuticals businesses.



**Henrik Kjær Hansen**

Henrik joined Novo Holdings A/S in January 2017 as a Senior Director, Principal Investments, leading investment process and taking part in managing and developing the growing portfolio of investments.



**Barbara Purcell**

Barbara is President of the Diversified Portfolio at multinational specialty pharmaceutical company Bausch Health and is a member of its Executive Management team. She has spent the past 25 years working in the pharmaceutical industry.

# Our leadership team



**Carl-Åke Carlsson**

Chief Executive Officer and  
President



**Daniel Schwartzlose**

President, Xellia International



**Craig Boyd**

President, Xellia North  
America



**Aleksandar Danilovski**

Chief Scientific Officer



**Bjørn Thonvold**

Corporate Vice President  
People & Organization



**Geelanie Briones**

Corporate Vice President  
Global EHS & Quality



**Hera Bragadottir**

Corporate Vice President  
R&D and Strategic Projects



**Jamie Iudica**

Senior Vice President  
Global Product Supply



**Kristin Lund-Mydahl**

Corporate Communications  
and Brand Management



**Matthew Anderson**

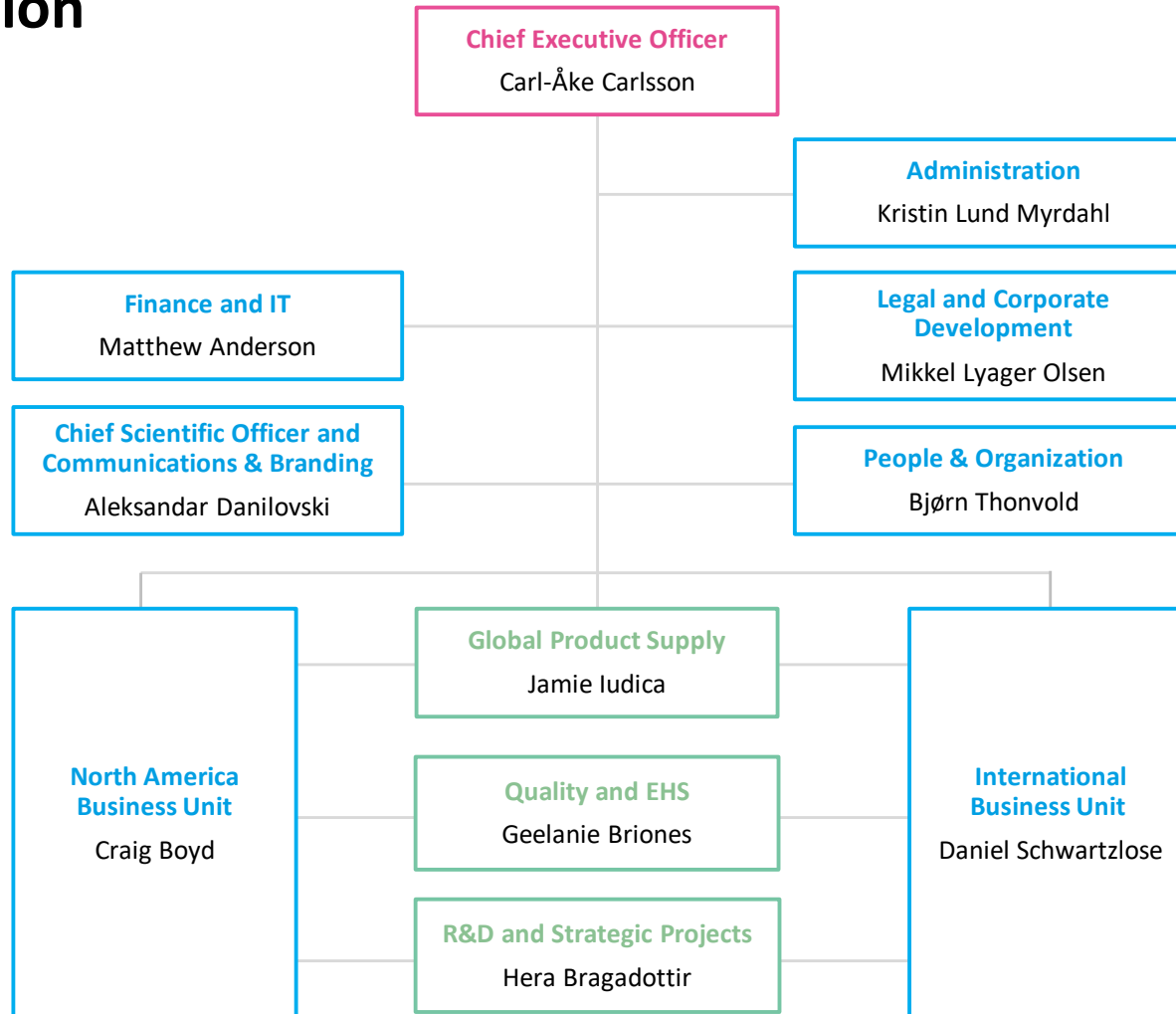
Chief Financial Officer



**Mikkel Lyager Olsen**

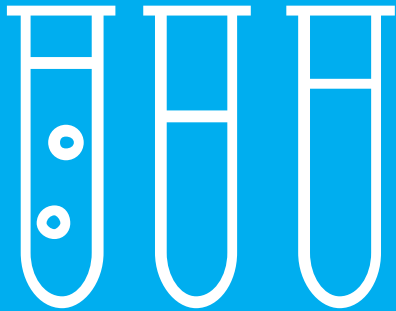
Corporate Development &  
Chief Legal Officer

# Our organization





Thank you!



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