



Delivering Capital Projects with a One-Model Approach

American Pharma Manufacturing
& Outsourcing Summit 2025



Becca Ford

Project Vice President

Fill & Finish Expansions Clayton, AP & PMO



*20 years experience
in capital delivery,
lean and marketing*



*Board Member for
LifeSmart Youth*



4x Starfish Mentor



*Cycling, hot yoga,
Bengals football*

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A love story for the ages

*In 2023, we celebrated the
100 years of innovation*

As a doctor living with diabetes, Marie Krogh realised the importance of the discovery of insulin. She convinced her husband, Danish Nobel laureate August Krogh, to travel to Canada and seek permission to produce this life-saving medicine in Denmark.

In **March 1923 the first patients in Denmark received insulin** manufactured by Krogh and his partner Hans Christian Hagedorn.

Today, the passion and determination of our founders continues to inspire us in everything we do and **we renew our commitment to drive change for a healthy world.**



August and Marie Krogh's
story reflects their love for
one another and for humanity



Building the future for patients

The need to scale



Growing demand
for GLP-1 products



New products and
formats to the
market



Need for future-
proofing our
facilities

We serve **45.2 million** patients
every day

**But millions more are still
untreated**



More than

500M

adults live with diabetes



Almost

1,000M

people live with obesity



Around

300M

people live with rare
diseases



Introducing Fill & Finish Expansions

BILGISSA BALDE
Type 1 diabetes
Guinea



NOVO

Establishing fill/finish facilities around the world



Clayton, NC, USA



Odense, Denmark



Chartres, France



Tianjin, China



Montes Claros, Brazil

Our environmental sustainability ambition



All suppliers use renewable power



Sustainably-sourced key materials



Operate with renewable energy



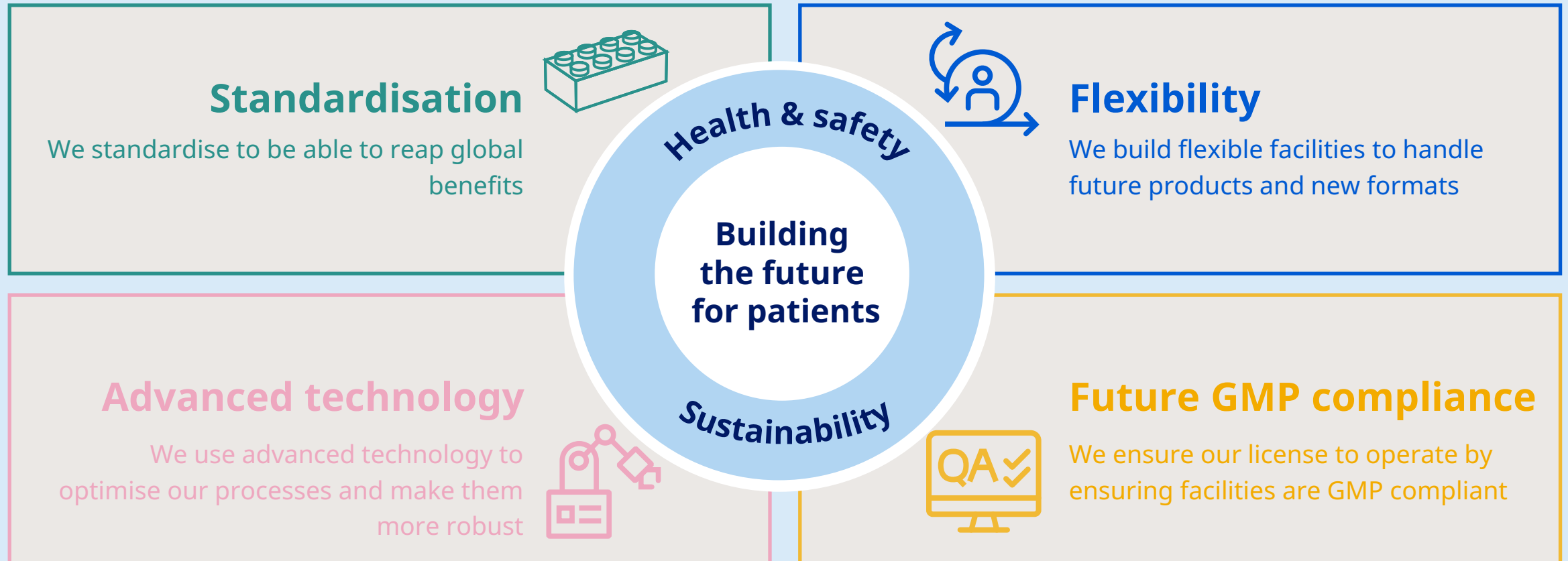
No resources wasted

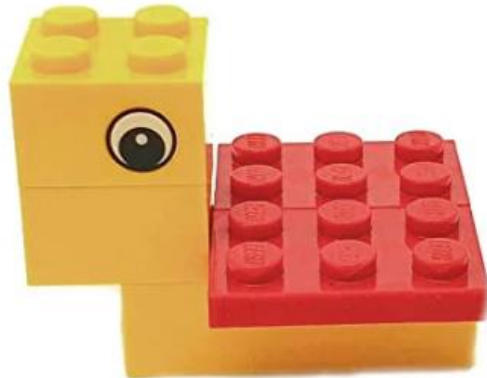
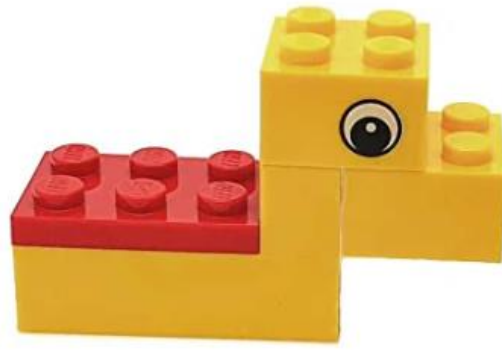


Flexible facility enabling repurposing

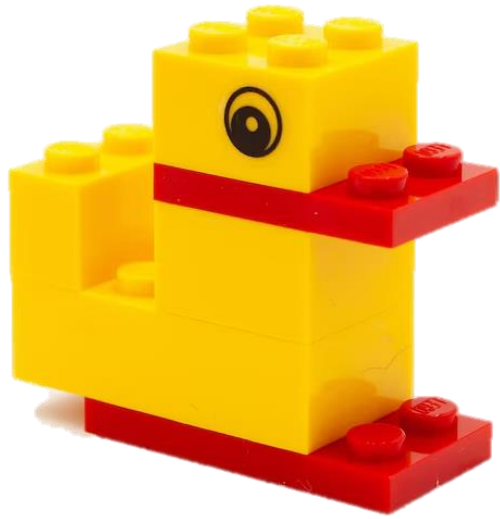


Our approach | Getting to more patients faster

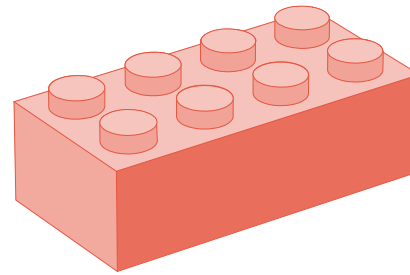




LEGO Duck Serious Play - 2000416

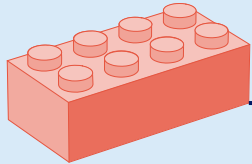


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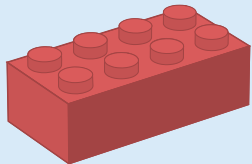


Standardisation | A modular approach

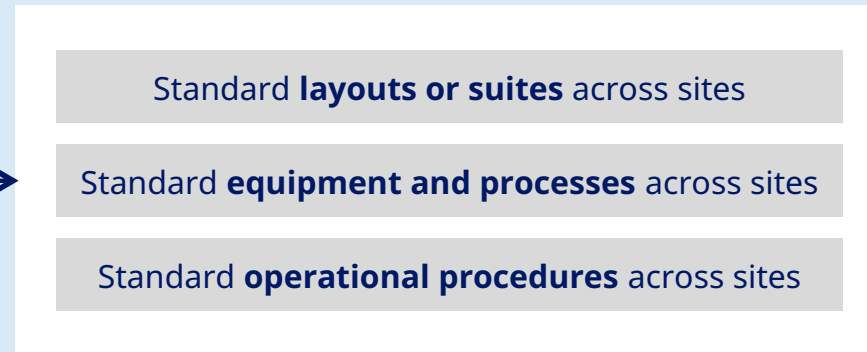
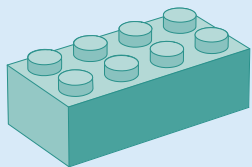
AP RTU Module



AP Bulk Module



FP Module



The modules are organised with full accountability for their scope



Global Facility Standards



Global Equipment Standards, incl. process development

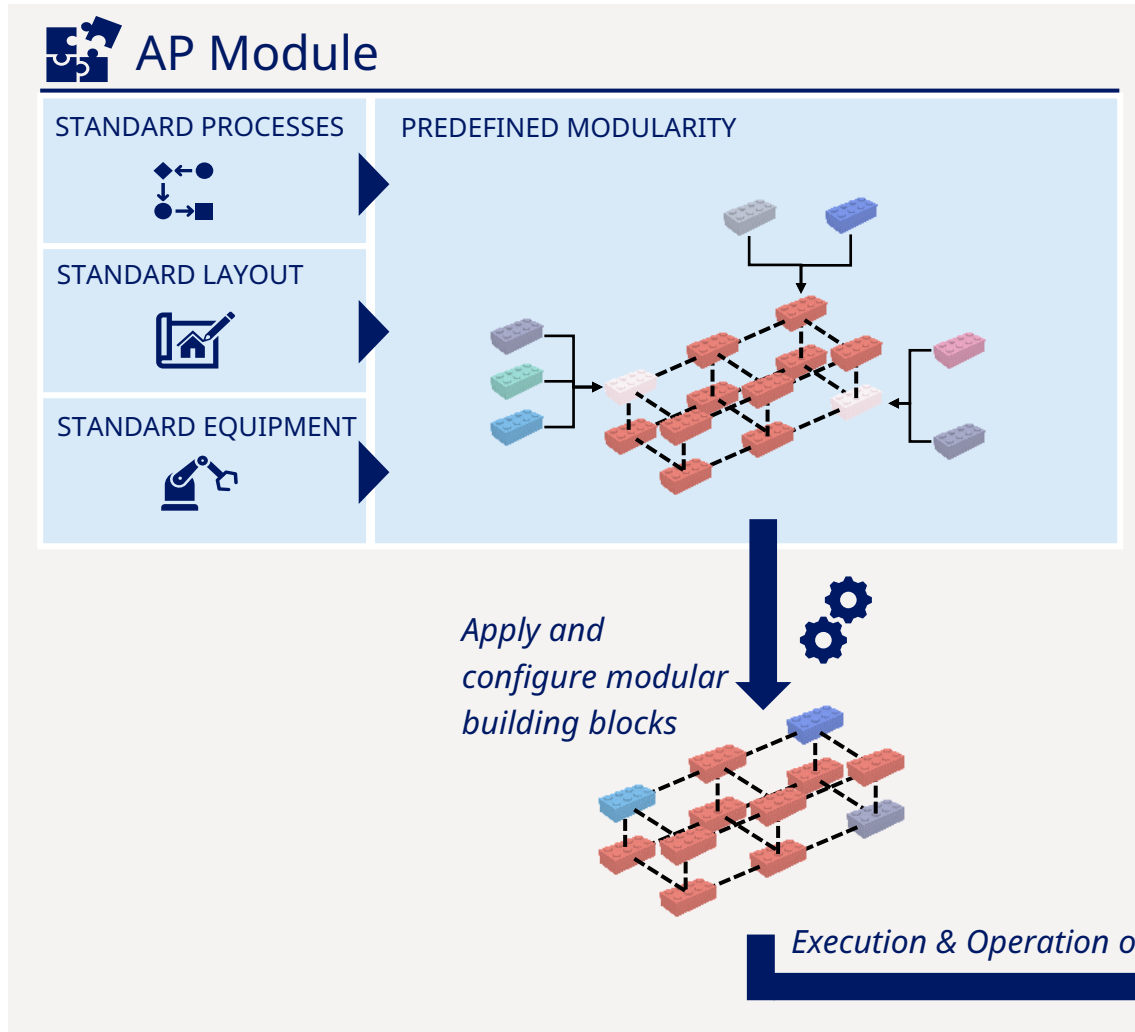


Global Operational Standards and ramp-up readiness

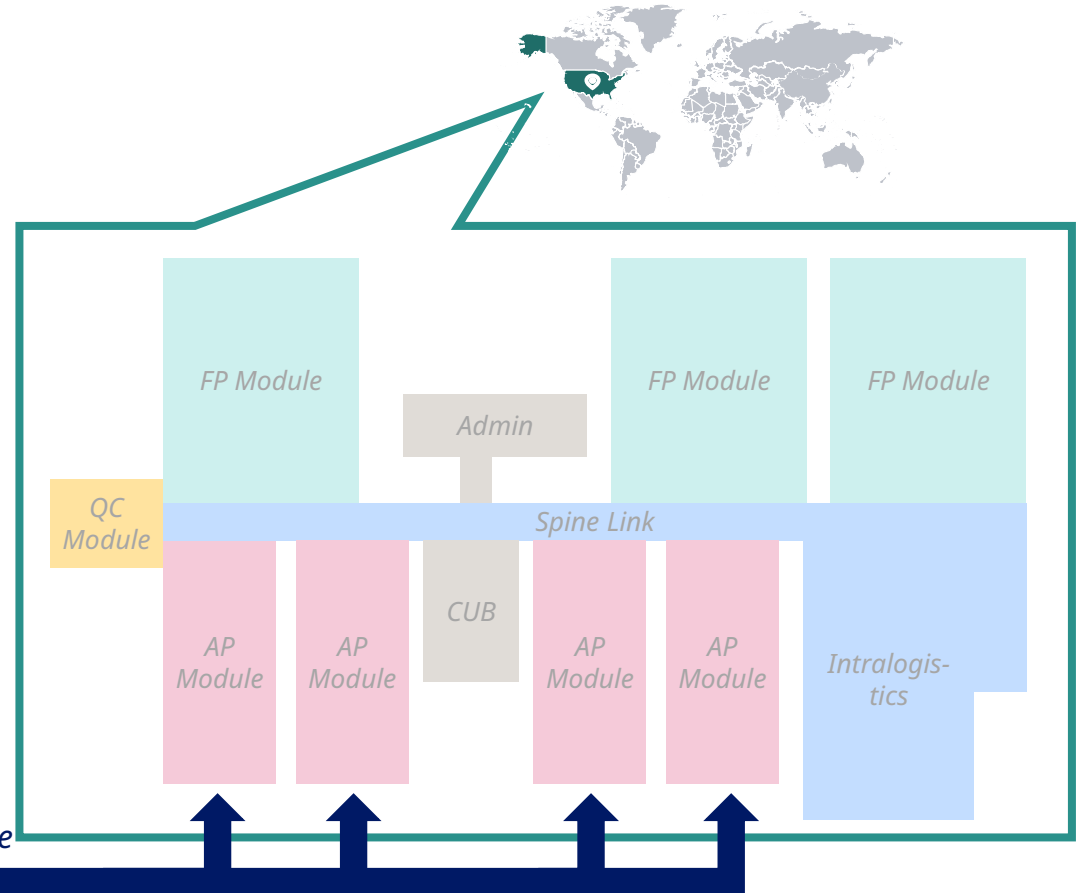


Global CQV standards, incl. CQV templates & leveraging guidance

AP Module | A composite standard



📍 FILL & FINISH SITE EXPANSION



AP Module | Standard Module Design Drivers



Unidirectional
flow of
personnel and
materials



Ready-to-use
primary
packaging
material



Closed
formulation
process after
addition of API



Isolator filling
line with reduced
activities in
Grade A



Continuous
viable
monitoring in
Grade A



Fully automated
high-frequency
material
handling in CNC



Grade A

Grade C

Grade D

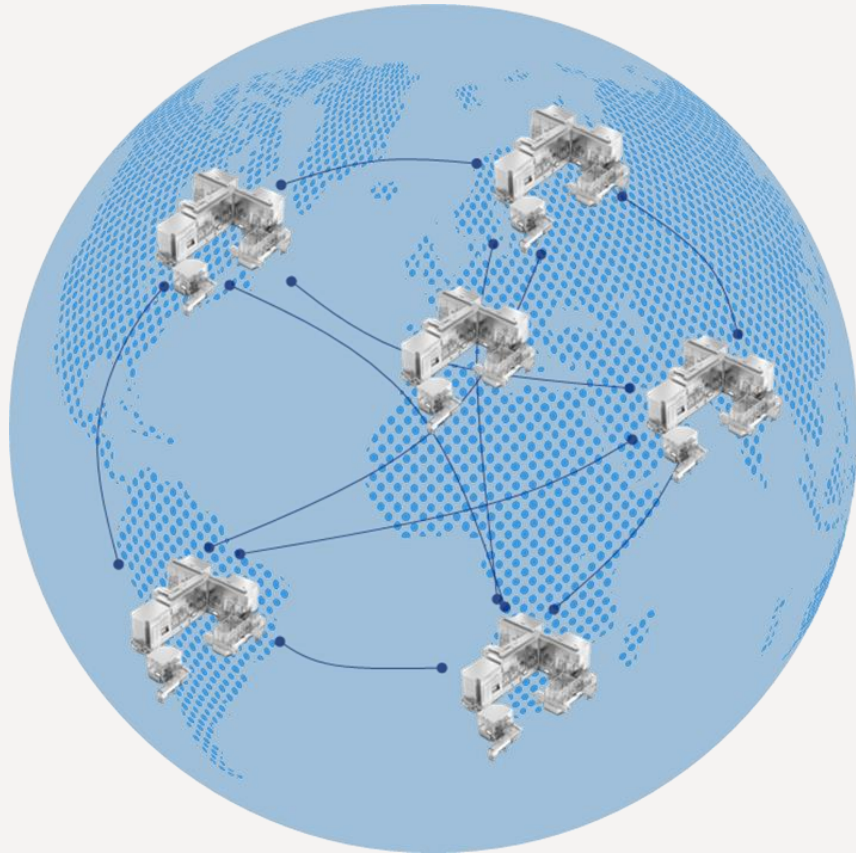
CNC area

Design one, build many | The fleet concept



Networks of fleets | Our tool to maintain the standard through the lifecycle

Network of fleets



Benefits of standardization



Truly global support



Strengthened process robustness

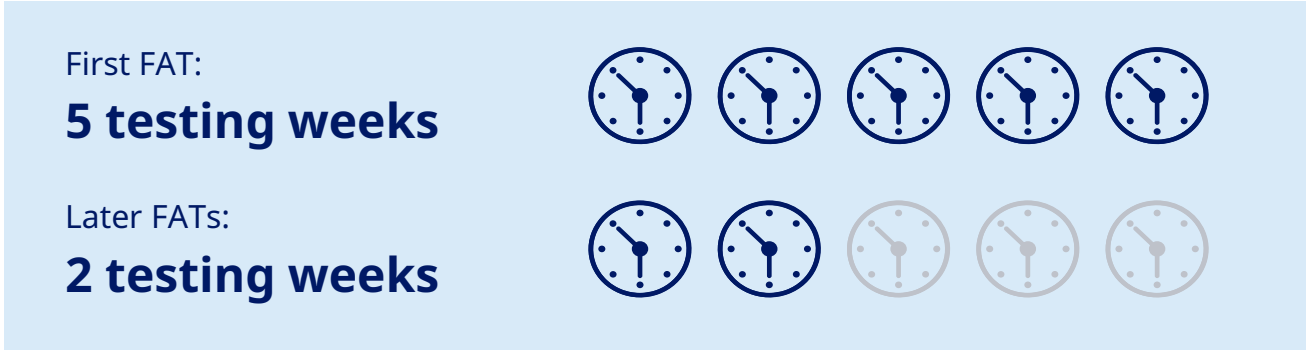


Shorter validation timelines



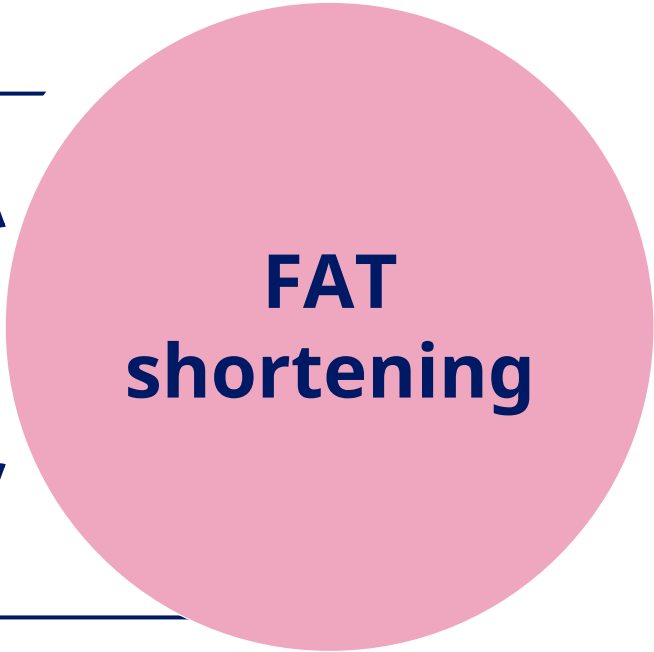
FASTER TO PATIENTS

Case Study | CIP/SIP fleet FAT shortening



Extensive testing **Leveraging**

Unit knowledge and testing **Maturity**



Case Study | CIP/SIP fleet FAT shortening

Leveraging

- **Functional testing:** 59% testing reduction
- **Software testing:** 67% testing reduction

Reduction from 3 weeks to 1 week

Maturity

- **Timeline optimization:** learned lessons from previous FATs led to significant timeline reduction
- **Deviation reduction:** design, manufacturing and testing maturity led to less changes and retest

Reduction from 2 weeks to 1 week



Fill & Finish Expansion Project



Clayton, NC



1.4 Million ft²



\$4.1 Billion Investment



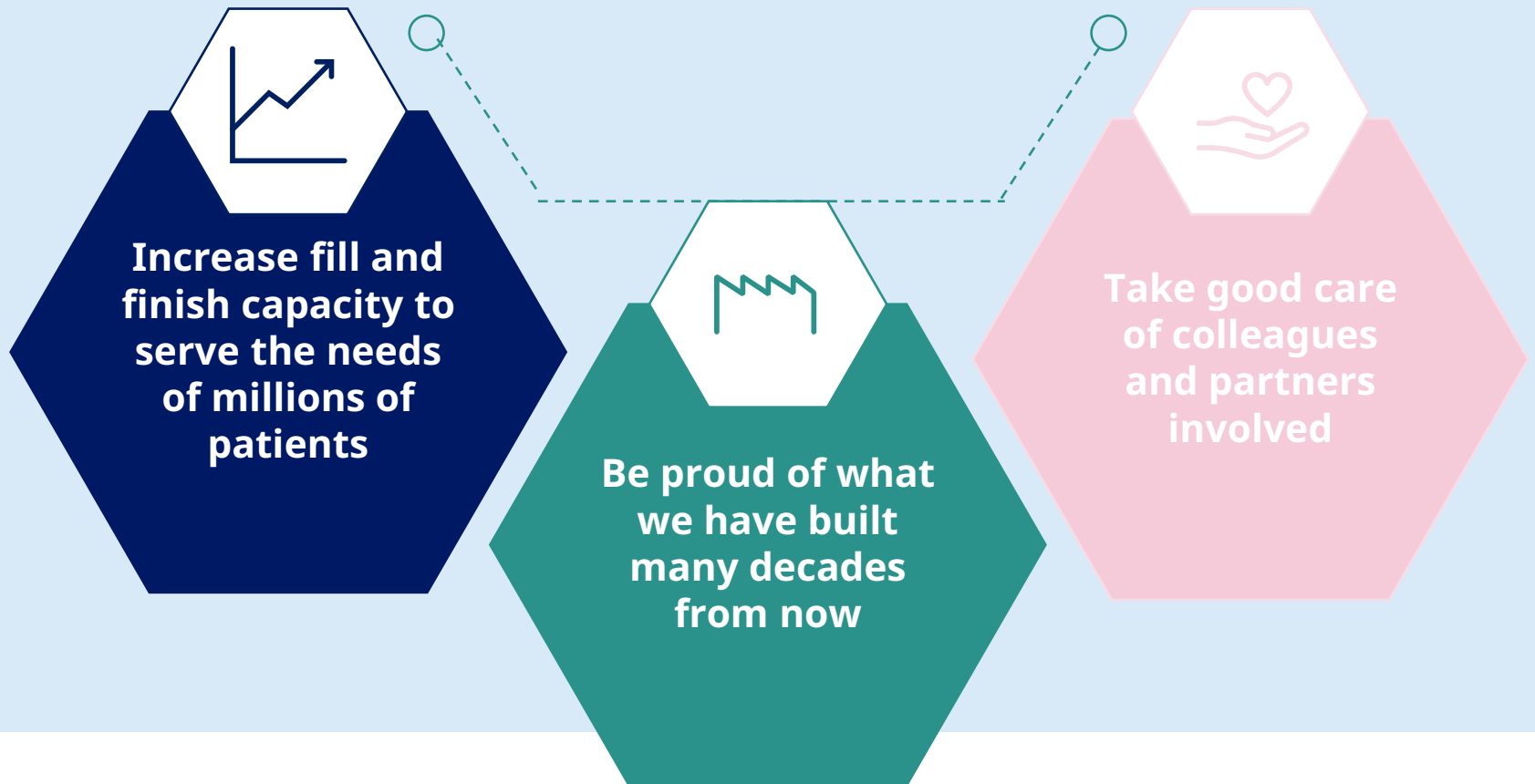
1,000 New Jobs in Johnston County



Over 2 Million Safe Working Hours



Our success criteria | Building the future for patients



KARLA MARINO
Karla lives with obesity
Mexico



Novo Nordisk Way

Driving change to defeat serious chronic diseases.

Sustainable business

Driven by our purpose

Questions?

A young boy with brown hair is hanging upside down from a blue and red rope. He is wearing a black t-shirt and black pants. He has a wide, joyful smile, showing his teeth. The background is a light-colored wall with a large, circular, woven wooden decoration. The floor is light wood. The word "Questions?" is written in large, white, sans-serif font across the middle of the image.