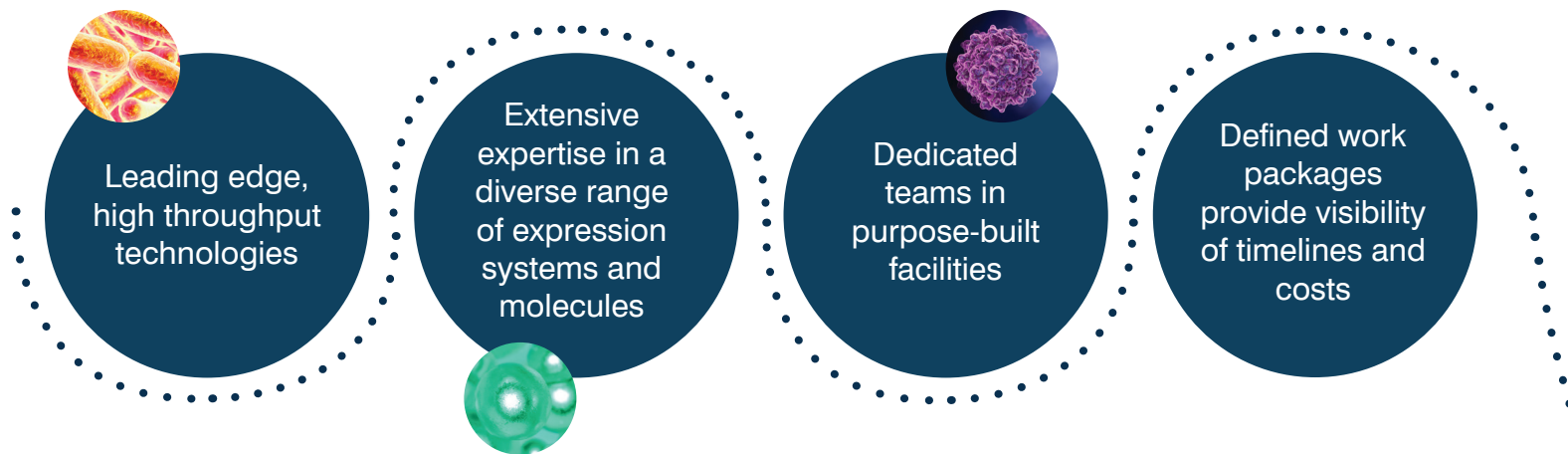


**PROCESS
CHARACTERIZATION
AND VALIDATION
SERVICES**

Your CDMO Partner Advancing Effective Submissions for Life-Changing Medicines

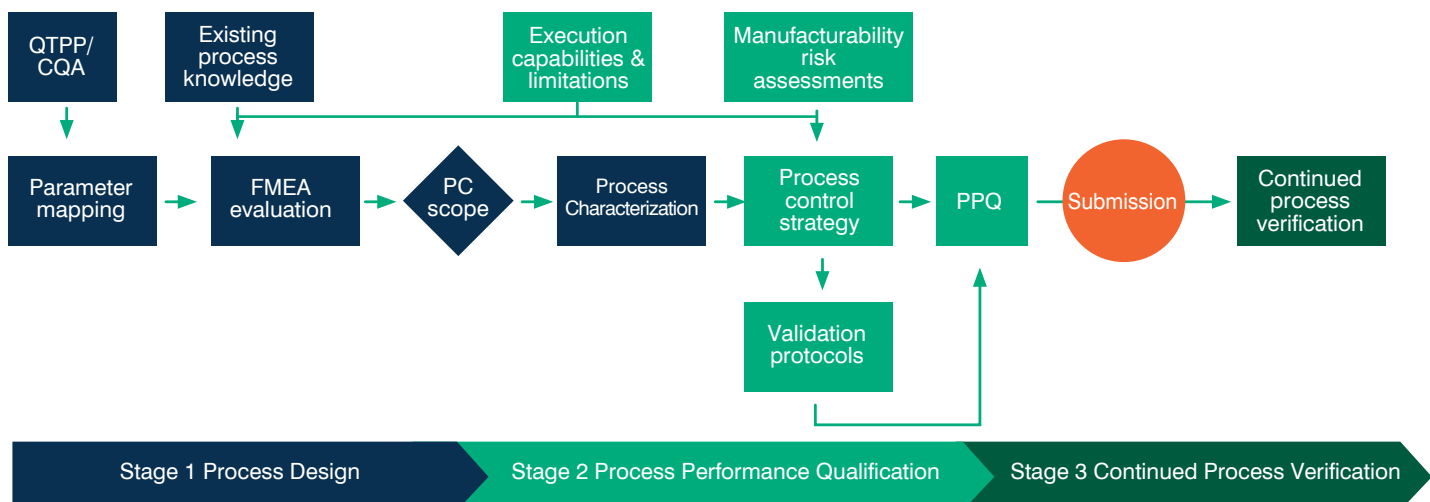


We deliver robust control strategies and successful Process Performance Qualification (PPQ) for long-term production for our partners' journeys.

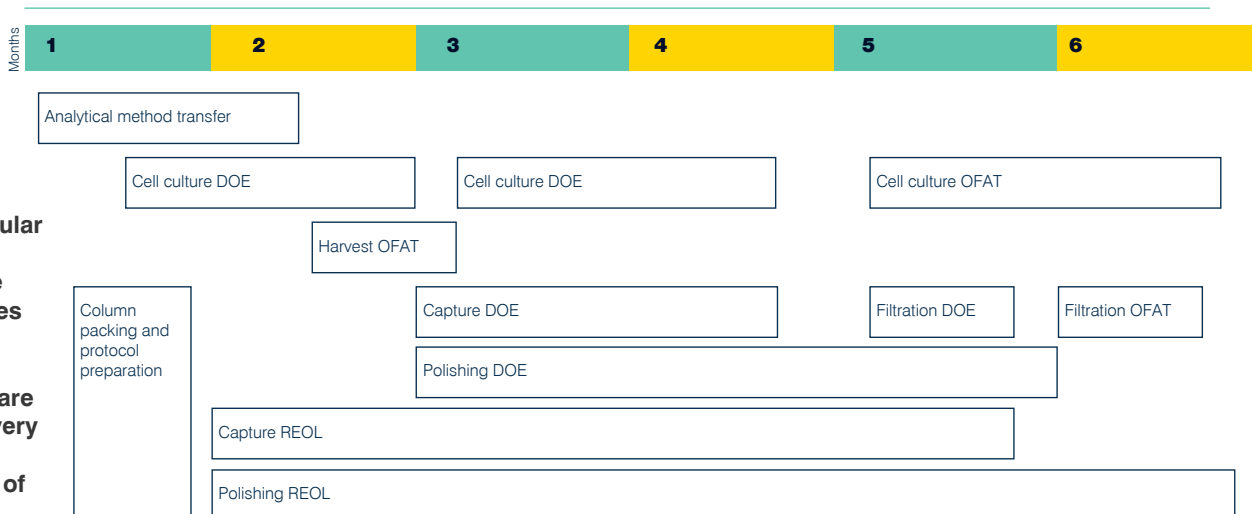
Facilities and Scientists Dedicated to Process Characterization Support:

- Failure Modes and Effects Analyses (FMEA)
- Analytical method qualification
- Unit operation screening and/or Design of Experiment studies
- Intermediate and media stability studies
- Resin and membrane reuse
- Robustness and/or linkage studies
- Scale down model verification
- Programs associated with process validation and commercial manufacturing
- Stand-alone process characterization programs

Extensive and recent approvals across a range of modalities for manufacturing scales 100 L to 20,000 L



Example process: **Cell Culture** → **Harvest** → **Capture** → **Polishing** → **Filtration**



Customizable, risk-based modular work-flows deliver effective control strategies for robust manufacturing processes that are capable of delivery throughout the entire life-cycle of your molecule.

Modular yet customizable approach

Process Characterization integrated into organization and offered as stand-alone service

Dedicated in-house statistical expertise

SMEs are thought leaders, and participate in groups shaping the industry

Our global network delivers agile solutions for our clients on their journey to commercialization for mammalian, microbial and advanced therapies

Thousand Oaks, CA, USA

College Station, TX, USA

Watertown, MA, USA

RTP, NC, USA

Holly Springs, NC, USA

Hillerød, DK

Billingham, UK

Wilton, UK

Darlington, UK

Our Global Facility Network

We offer accessibility and flexibility in choice of locations. Our Billingham, UK and RTP, NC (USA) sites house facilities dedicated solely to Process Characterization.



Our standalone service means we work closely with your technical experts on designing small-scale studies to demonstrate compatibility and support your process validation efforts. Read about subcontracting PC studies in our blog.

Partners for *Life*

Contact us to discuss your science.

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3940 Fujifilm Way
College Station, TX 77845
+1 979 431 3500

USA

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100 Biotechnology Avenue
Holly Springs, NC 27540
(Coming online 2025)

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