

# CDMO Evaluation Scorecard

## TECHNICAL CAPABILITY

- Direct and specific experience manufacturing medical devices similar to yours
  - Sufficient cleanroom classification level and capacity
  - Demonstrated specialist process capability required to manufacture your medical device
  - Sufficient metrology and inspection capabilities for your medical device
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## QUALITY SYSTEM

- ISO 13485 certification that covers the processes and product types relevant to your medical device
  - CAPA system effectiveness, especially in relation to identifying and resolving root causes
  - Internal audit programme (this helps demonstrate quality system maturity and a continuous improvement approach)
  - Good FDA and regulatory inspection history
  - Robust processes for handling receiving, investigating, and escalating complaints and other issues
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## PROJECT AND TRANSFER CAPABILITY

- Medical device technology transfer experience
  - Robust, formalised, and proven project management capabilities
  - Good depth of engineering expertise and a stable team
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## REGULATORY AND COMPLIANCE

- Regulatory capabilities including the ability to support change notifications, regulator queries, and regulatory submissions
  - Robust change control processes covering manufacturing processes, materials, and equipment
  - Good design and manufacturing documentation standards
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## COMMERCIAL AND OPERATIONAL

- Financial and structural stability
  - Capacity headroom to meet your needs today and in the future as you achieve your growth targets
  - Supply chain and supplier management capabilities
  - Geographic location, including the quality of the wider medical device ecosystem at the CDMO's location
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## RELATIONSHIP AND CULTURE

- Communication style and responsiveness
- References, particularly from customers with a similar medical device or who went through a similar technical transfer
- Willingness to engage meaningfully when negotiating quality agreement terms