Life Science
CCI Services

pti science of quality

Expert Support for Container Closure Integrity

PARTNERING WITH pti science of quality

Risk Reduction

Mitigate regulatory findings with deterministic, inspection-ready methods

Speed of Validation

Proven track record of shortening timelines from setup to full GMP compliance

Depth of Expertise

Decades of leadership in deterministic CCI, with active roles in USP <1207> and <382>, Annex 1, and ASTM standards

Global Assurance

Dual Centers of Excellence (New York & Switzerland) deliver continuity and compliance worldwide

Life Science
CCI Services

Testing, Training & Consulting Services
Test Method Development Support
Validation Support and Deployment

Our expertise and services ensure your products meet the highest standards of performance and regulatory compliance

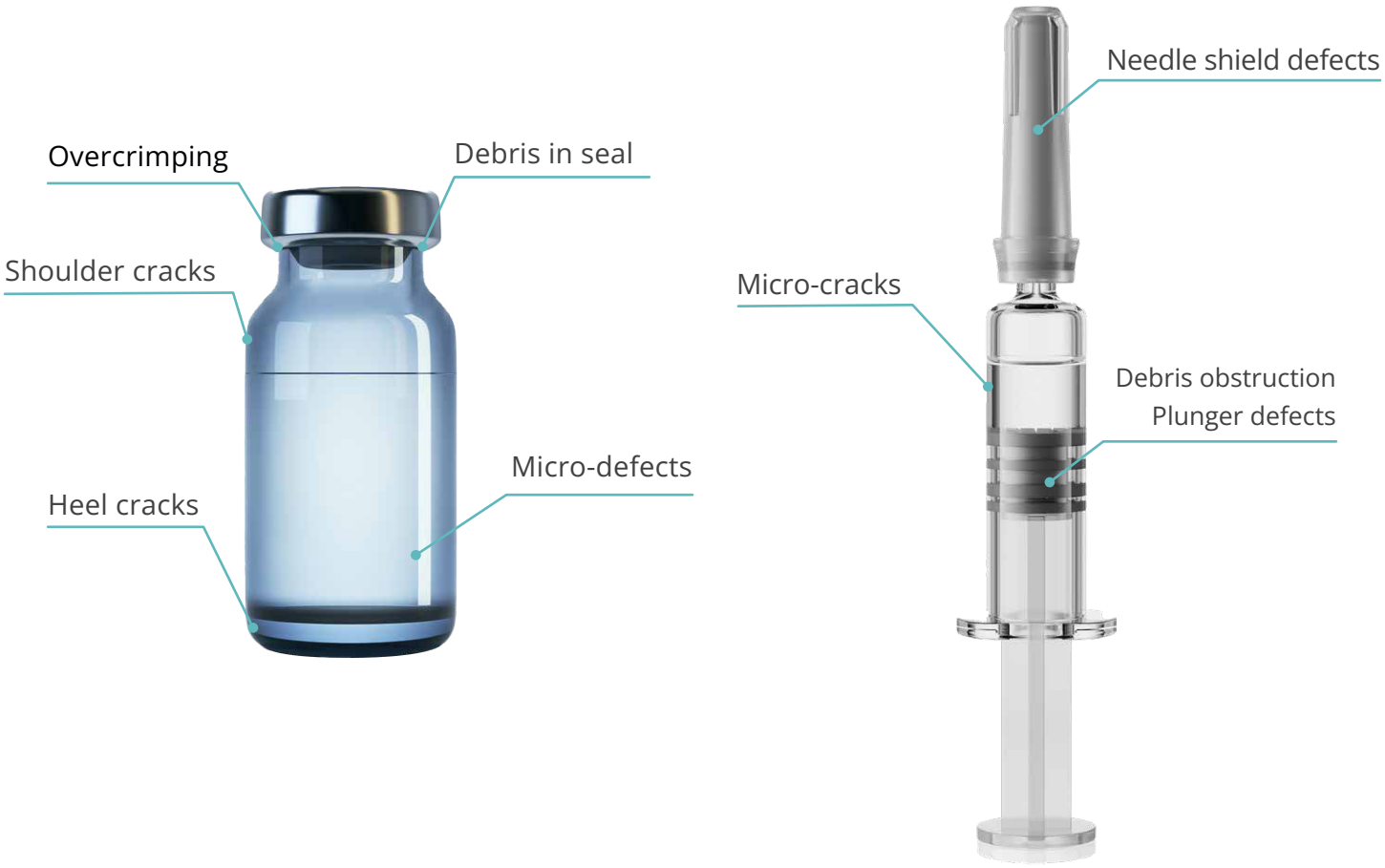
1 Initial Recipe Creation (IRC) & Recipe Optimization

Build a strong foundation for reliable CCI testing – reduce risk early.

- Define initial method parameters and pass/fail acceptance criteria, lowering the chance of regulatory rejection later.
- Conduct positive and negative control measurements to establish clear, reliable differentiation between intact and leaking containers
- Establish a robust starting point that accelerates method development and reduces costly rework.

Deliverable
Comprehensive report with recommended method parameters and reject references that give clients a clear pathway to development from the outset.

DEFECT DETECTION



2 Test Method Development & Validation

Accelerate time to compliance with optimized, reproducible methods.

- Establish system suitability along with statistically significant control sets, avoiding method variability.
- Define all validation parameters, including Limit of Detection (LOD).
- Provide USP <1207>a–compliant protocol templates for TMD and TMV, reducing client workload and audit exposure.
- Execute at PTI labs or on-site, with expert executing and/or coaching from PTI to ensure successful method transfer.

Deliverable
Validated, GMP-compliant CCI method with full documentation shortening timelines to regulatory acceptance and inspection.

3 Helium Testing Services

Unmatched sensitivity and credibility.

- Ultra-sensitive leak detection with quantifiable results to satisfy regulators and sponsors.
- Support R&D, material selection, equipment qualification, and QC programs, ensuring decisions are backed by quantitative data.
- Cold-temperature testing capability (–20°C to –180°C) for advanced formulations and cryogenic storage
- Flexible programs from small studies to large-scale validation, fitting both biotech startups and commercial manufacturers.
- Aligned with USP <382> for elastomeric component integrity testing, ensuring robust evaluation of closures and critical materials.

Deliverable
Clear, actionable data on package integrity, benchmarked against Maximum Allowable Leakage Limits (MALL) and accepted worldwide by regulators and sponsors.

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