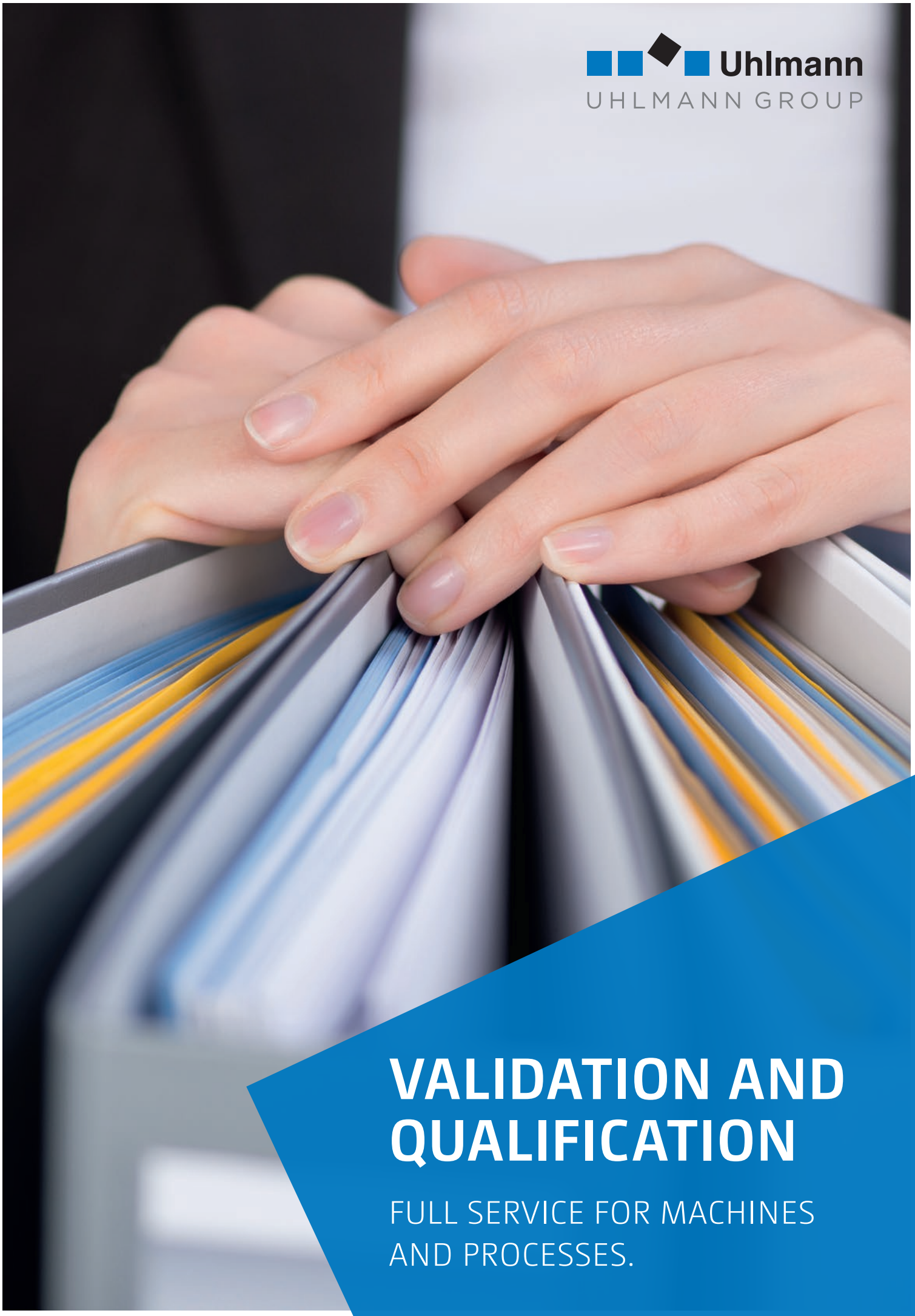

Uhlmann
UHLMANN GROUP

VALIDATION AND QUALIFICATION

FULL SERVICE FOR MACHINES AND PROCESSES.

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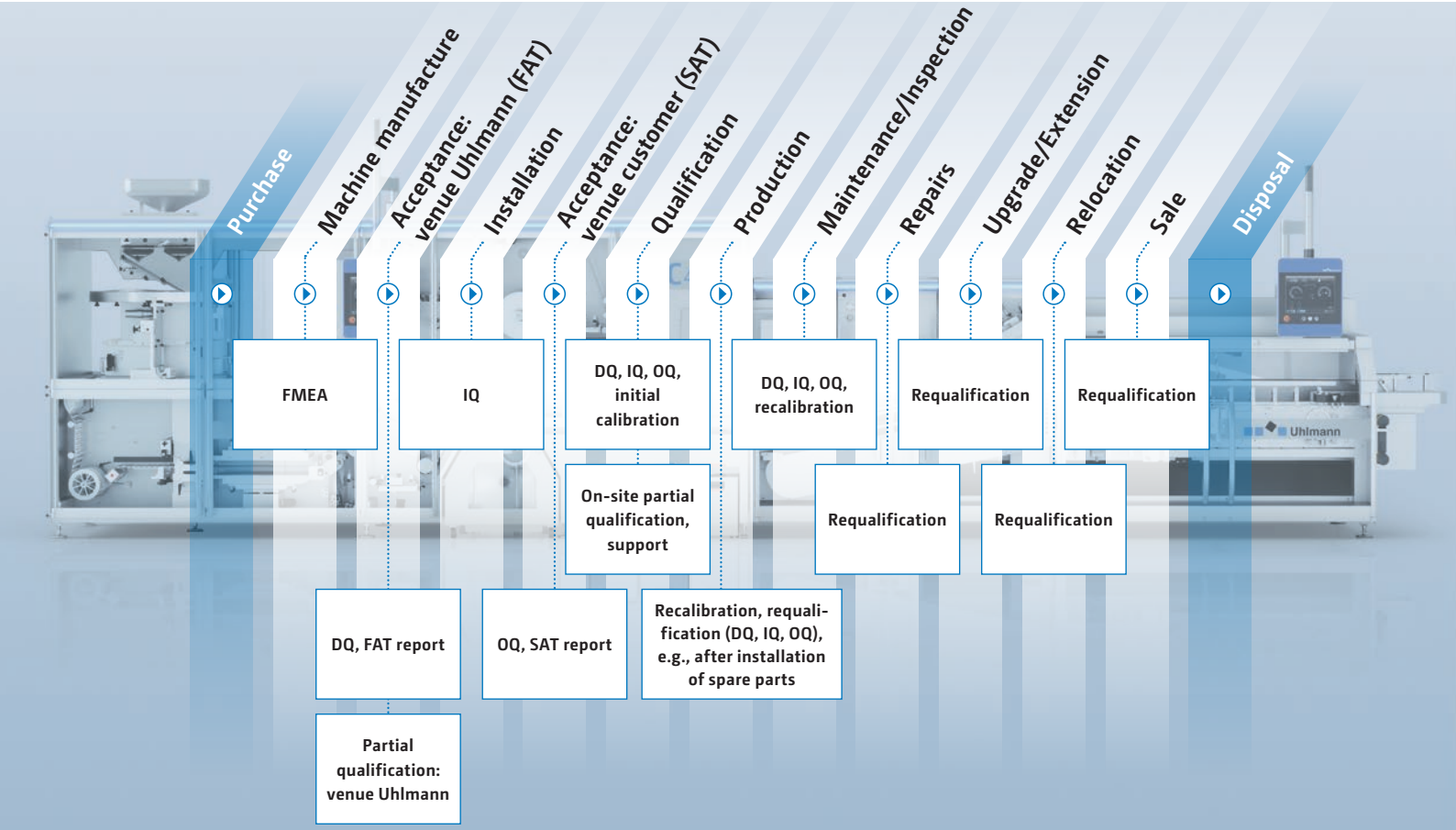
VALIDATION AND QUALIFICATION

You would like to put your new Uhlmann machine into operation quickly, or soon resume production after an upgrade or update? You want to be assured that your machines are operating flawlessly and package products to a consistently high standard of quality? And you are well prepared for audits required by the FDA or other regulatory authorities? All of this should involve minimum effort and manageable costs? Our experts undertake these measures for you, drawing on experience gained from many successful validation and qualification projects. This capability of ours has been confirmed in a survey: the quality and customer-specific versions of qualification documentation and the expertise of our team received very positive ratings. Trained by an accredited body, our technicians and engineers perform all measures in compliance with established standards (e.g., GMP, GAMP 5) and according to your specifications, providing all data and documents required for validation. The full qualification package includes DQ, IQ, and OQ. Further service modules can be supplemented for tailor-made solutions.

WE TAKE CARE OF THE FOLLOWING FOR YOU – OVER THE ENTIRE LIFE CYCLE OF YOUR PACKAGING MACHINES AND LINES:



URS = User requirement specification: definition of all requirements to be met by the system

DQ = Design qualification including:
- HDS – Hardware design specification: specification of the hardware components in the machine, e.g., operating system with performance data
- SDS – Software design specification: specification of the installed operating/control and IPC software components
- FMEA – Failure mode and effects analysis. Risk analysis including evaluation of the following criteria: probability of occurrence, detection, and significance

IQ = Installation qualification: documents the correct implementation of the previously defined specifications concerning the assembly and installation of the supplied machine

OQ = Operational qualification: tests the correct functioning of the separate components of a machine/equipment

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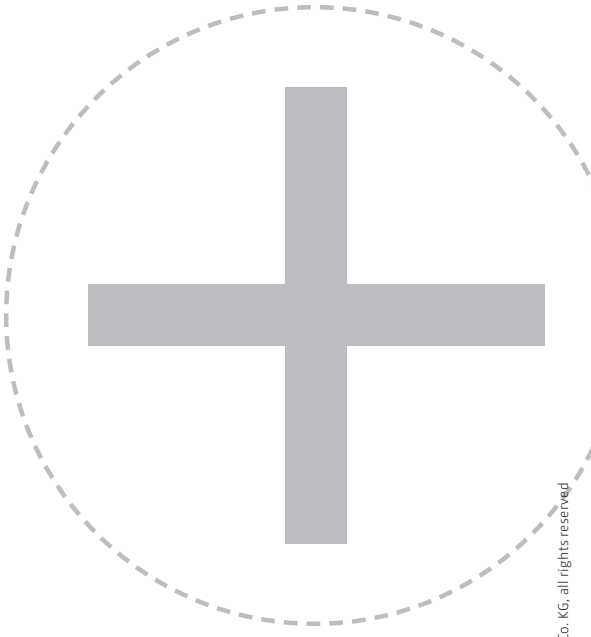
VALIDATION AND QUALIFICATION

CONVINCING SERVICES

- Validation and qualification of new machines – with qualification included as an integral part of the quote
- Retrospective qualification of existing equipment
- Requalification of machines after an upgrade/update
- Qualification of machines from other manufacturers
- Turnkey qualification: master plan, risk analysis, installation qualification and operational qualification, computer validation, loop tests, SCADA validation, testing of 21 CFR Part 11 compatibility
- Consultation and support from a team of specialists
- In-depth understanding and knowledge of machines and processes
- Effective testing due to previous verification on the customer's system
- Adherence to schedules, planning reliability, cost transparency



YOUR ADDED BENEFITS

- Workload reduced – no internal resources required, one-stop completion of the entire qualification process
- Time saved – much shorter qualification process and faster (re-)commissioning
- Well prepared for audits – with seamless documentation of the qualification process
- Legally compliant validation and qualification – on the basis of established standards and specifications
- Reliable packaging – perfect processes for top quality over the entire life cycle of the equipment

Learn more about
Uhlmann Customer Services.
https://www.uhlmann.de/services

THE HEARTBEAT OF PHARMA PACKAGING

To find our locations worldwide
please visit **www.uhlmann.de**

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