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CHECKLIST
SAFE VALIDATION

- [ ] Depending on the intended use of the product, the requirements should be validated in advance of the production process.
- [ ] Validation ensures a safe and robust production process that delivers reliable results over the life cycle of the product.
- [ ] Process validation is always carried out when product properties on the finished product cannot be verified non-destructively - or verification is too too costly.
- [ ] The validation plan (VP) is a detailed document that clearly specifies the entire validation process
- [ ] Plans for validation should be detailed, monitored and ensure that sufficient resources are made available.
- [ ] A process requiring validation is qualified in three phases. Planning (VP), Execution (IQ-Installation Qualification, OQ-Functional Qualification, PQ-Performance Qualification) and Evaluation (FR).
- [ ] The final report (FR) provides a summary of the validation process, results and assessment . Also Pass or Fail.

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SAFE VALIDATION - WE SUPPORT YOU!

You need to validate but don‘t know how to do it?

- We will support you with our expert knowledge in process validation for plastic components in medical technology.
- We have many years’ experience in carrying out validations in the field of medical technology.
- We are a long-standing partner in medical technology and a full service provider for the development medical components made from plastic.
- We manufacture in clean rooms of ISO classes 6,7 and 8 and are certified according to DIN EN ISO9001 and DIN EN ISO 13485:20106.

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