These quality processes are the basics to prepare an unlicensed medicine

- Certificates of Analysis and Conformity
- Premises licensed and inspected by - MHRA

These additional quality standards are expected of commercial manufacturers by the MHRA

- Incoming analytical and micro testing (raw materials, packaging, equipment)
- Stability data generation (to ICH standard)
- Validation of all analytical and micro methods
- Supplier Management programme (inc. audits)
- Falsified Medicines Directive programme in place

Additional quality standards for commercial manufacturers by the MHRA

- Training
- Computer systems validation
- Recall and Complaints procedures
- Validation (facility, cleaning, process and equipment)
- Preventative maintenance programmes
- CAPA plans and Continuous Improvement activities

This is the same as for licensed pharmaceutical manufacturers

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These additional quality standards are expected of commercial manufacturers by the MHRA