

# VMD TEMPLATE

[Name of Business]

## Proposed Agenda for GMP Inspection

[Time] [Date]

### 1. Opening meeting

- Introductions
- General update from the VMD
- Company and site background (to include product range and background)
- Scope and confirmation of agenda
- Follow up from last inspection

### 2. Familiarisation Tour

### 3. Review of Manufacturing Authorisations and GMP Certificate

### 4. Site master file / site plan review / site familiarisation tour

### 5. Pharmaceutical quality system

- Quality Policy
- Change control including procedure and log of changes since the last inspection
- Deviation handling including procedure and log of deviations since the last inspection
- Corrective and preventative actions including procedure and log of CAPAs since the last inspection
- Out of specification investigations including procedure and log of investigations since the last inspection
- Product Quality Review
- Quality Risk Management

### 6. Personnel

- Key Personnel
- Training
- Gowning requirements

### 7. Premises and Equipment

- Access and security
- Pest control measures
- Temperature/ Humidity controls

\* Agenda is for guidance only and may be subject to modifications

- Equipment validation
- Cleaning validation

## **8. Documentation system overview**

- Structure and controls
- Starting & Packaging Material specifications
- Intermediate & Bulk Product specifications
- Finished Product Specifications
- Archive arrangements

## **9. Production**

- Production facilities
- Production areas/processes including warehouse
- Goods In checks
- Sampling and Testing
- Inventory control system
- Area Clearance
- Batch Record review
- Distribution controls
- Waste disposal

## **10. Quality Control**

- QC facilities
- Packaging material and label controls
- Supplier Assessments
- TSE statements
- On-going stability arrangements
- Reference and Retain samples
- Batch Release

## **11. Outsourced activities**

- Technical Agreements

## **12. Complaints and Product Recall**

- Complaint and Recalls process

## **13. Self-inspection**

- Procedure and Schedule

## **14. Any other business**

## **15. Preparation for wrap up meeting**

## **16. Wrap up meeting**

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