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| **DCR INITIATION** |
| DCR Number |  | Due Date |  |
| Doc ID and Title(s) | QP806\_Analysis of Data |
| Current version # | **12.0** | New Version # |  |
| Document Type:  | [x]  SOP [ ]  Workbook/Checklist [ ]  Tech. Doc | [ ]  Training document [ ]  Form [ ]  Other: | Change Type: | [ ]  New [x]  Change[ ]  Obsolete  |
| **Description of change(s) to document:** |
| General review of the procedure, update of Technical Support metrics, addition of the review of trends in QC metrics and Post Market Surveillance data. |
| **Impact Assessment / Risk Analysis:**  |
| Does this change impact any other documents? [x]  N/A | [ ]  SOP [ ]  PI [ ]  IFU [ ]  Forms [ ]  Training Material  [ ]  Other:  |
| Is this this change related to a Quality process? [x]  N/A | [ ]  Change Control [ ]  NCR [ ]  CAPA [ ]  PMS [ ]  Audit[ ]  Other:  |
| Types of training to be utilised: | [x]  Read and acknowledge [ ]  Presentation [ ]  Notification [ ]  Other:  |
| Review Required  | [x]  Operations [ ]  R&D [x]  Quality [x]  Regulatory [x]  Tech. Support [ ]  Other: |
| **APPROVALS: AUTHORISATION FOR RELEASE AND DISTRIBUTION** *(Add rows if required)* |
| **Name** | **Department** | **Signature** | **Date** |
| **Author/Subject Matter Expert** |  |  |  |
| **Document/Process Owner**  |  |  |  |
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| **ISSUANCE** *(QA/Authorised Issuer to complete)* |
| **New SVN #** |  | **Effective Date** |  |
| *FM401-1* updated? | [ ]  Yes  | *FM605-12* updated*?* | [ ] Yes [ ]  N/A |
| Superseded version replaced & filed?  | [ ]  Yes | [ ]  N/A |
| Obsolete doc(s) removed from circulation? | [ ]  Yes | [ ]  N/A |
| *QP012* Read & Acknowledgment form initiated? | [ ]  Yes | [ ]  N/A |
| Workbook Verification Attached? | [ ]  Yes | [ ]  N/A |
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