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| **DCR INITIATION** | | | | | | | |
| DCR Number |  | | | | Due Date |  | |
| Doc ID and Title(s) | QP704\_Change Control | | | | | | |
| Current version # | **16.0** | | | | New Version # | 17.0 | |
| Document Type: | SOP  Workbook/Checklist  Tech. Doc | | Training document  Form  Other: | | Change Type: | New  Change  Obsolete | |
| **Description of change(s) to document:** | | | | | | | |
| H. Meraj updated section 7.8 to remove reference to Forms never issued for use. K. Hunter updated RA Manager responsibilities. Add RDC ANVISA 665/2022 | | | | | | | |
| **Impact Assessment / Risk Analysis:** | | | | | | | |
| Does this change impact any other documents?  N/A | | | | SOP  PI  IFU  Forms  Training Material  Other: | | | |
| Is this change related to a Quality process?  N/A | | | | Change Control  NCR  CAPA  PMS  Audit  Other: | | | |
| Types of training to be utilised: | | | | Read and acknowledge  Presentation  Notification  Other: | | | |
| Review Required | | | | Operations  R&D  Quality  Regulatory  Tech. Support  Other: | | | |
| **APPROVALS: AUTHORISATION FOR RELEASE AND DISTRIBUTION** *(Add rows if required)* | | | | | | | |
| **Name** | | **Department** | | **Signature** | | | **Date** |
| **Author/Subject Matter Expert**  **K. Hunter** | | **RA** | |  | | |  |
| **Document/Process Owner**  **John Morri** | | **QA** | |  | | |  |
| **QA Approval / Delegate** | |  | |  | | |  |

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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| Superseded version replaced & filed?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 |
| **Authorized Issuer** | **Name** | **Signature** | **Date** |
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