DIVISION/DEPARTMENT: MMD/Biotech	MSD	JD DOCUMENT CODE/ REVISION MMD/B1O/026 Rev 00
REPORTS TO (POSITION TITLE) Senior Manager, Operations	JOB DESCRIPTION	EFFECTIVE DATE: 22 Jan 2020
BAND/PATHWAY/LEVEL: 300/P1	POSITION TITLE: Operations Support Specialist	PAGE:

JOB PURPOSE

The Operation Support Specialist coordinates and supports all manufacturing related activities for the IPT. These activities include:

- Assist the Production Supervisors in the allocation of resources to meet agreed production plan (through weekly Planning meetings) and prioritize any other shop floor ad-hoc activities.
- Assist Production supervisor in management of compliance and technical skills training for shopfloor staff
- Completes post manufacturing batch documentation review and leads initiatives to improve straight through documentation.
- Acts as the IPT SAP Super-User; coordinates SAP shutdown maintenance and supports all SAP inventory updates and reversals.
- Data collection - for APR, Profit planning and management of Tier process.
- Prepares and issue necessary documents for production use. These documents are the batch records, manufacturing labels and other essential documentation related for production such as SOPs and Job Aids.
- Leads the changes executions for manufacturing documentation in liaise with other departments in Pharm such as PTO/Process Engineering, Quality and Manufacturing. This includes emergency changes related to the batch documentation when needed.
- Supports development of a continuous improvement framework within the overall IPT improvement program.
- Processing of POs for non-SOM items to support IPT operations.

MAIN RESPONSBILITIES

1. Manufacturing Excellence

- Prepares and issue necessary documents on a timely manner for manufacturing use.
- Supports document revision (SOP, Forms and etc.) when necessary to improve the system of documentation review, issuance and preparation.
- Completes manufacturing batch record review in accordance with cGMP requirements.
- Maintains the proper filing and safe keeping of all relevant manufacturing documents and have it available when needed including controlled copies.
- Support & manage Manufacturing Aids.

Batch Documentation Reviews

- Completes post manufacturing batch documentation reviews
- Provides straight-through document accuracy metrics and leads associated improvement initiatives

SAP & MES User and Inventory Updates

- Raise WOs, TR and GI materials.
- Test script execution for MES changes to MBR
- Ensures SAP inventory accuracy and supports manufacturing related stock adjustments and/or reversals

Others

- Data collection and metric tracking to support Tier process
- Update APR and CPV or equivalent.

2 Continuous Improvement (CI)

- Utilizes Lean Six Sigma Tools (Six Sigma, Kaizen, SMED, 5S etc) to support execution of continuous improvement projects to increase agility, flow, throughput and reduce cycle time and inventory
- Initiate CI activities in area of responsibility - Batch document simplification, SOP & JA process review

etc.

3. Quality

- Ensures that all assigned task related to manufacturing documentation support is in accordance with good manufacturing practices.
- Prepares or update SOPs and related documents to ensure compliance with regulatory standards.
- Actively engages in audits and supports implementation of agreed follow-up actions.

4. Safety, Health & Environment

- Ensures that all assigned daily manufacturing activities are planned and carried out in accordance with SHE requirements
- Participates in (as required) and supports the implementation of actions for all incidents Investigations and Audits
- Ensures all permitting requirements are met for all IPT maintenance activities on the day shift
- Promotes SHE leadership behaviours and engages employees at all levels on SHE issues
- Ensure Incident Investigations and Audits are fully supported with improvement actions implemented

5. People Excellence

Self

- Demonstrates leadership behaviours in alignment with the Merck leadership standards
- Take ownership of own career development opportunities and actively seek to improve both technical and "soft" skills
- Ensures both operational knowledge and technical skills are maintained and compliant against individual job program

ACCOUNTABILITIES	DIRECT IMPACT ($)*	INDIRECT IMPACT ($)*
NA	NA	NA

* *(only if applicable.)*

SUPERVISORY RESPONSBILITIES:	**No. of direct reports:** Total: 1 direct (Refers to the no. of staff reporting directly to this position) **No. of indirect reports:** Total: **0** indirect (Refers to total number of staff reporting to this position's direct reports) *(The headcount figure is subjected to ±10% fluctuation In view of chanaina business needs.)*

PROFILE:	**Qualification:** • Diploma qualification **Experience/Technical Skills:** • 3 - 4 years (preferred) in an operations environment with experience in documentation preparation and control preferred • Good knowledge in applicable regulations and divisional policies/guidelines (especially Cleaning/Housekeeping/Maintenance, Environmental Control, Process/Cleaning/ Equipment Validation, Change Control and Manufacturing Practices) • Good stewardship awareness (includina cGMP, reaulatorv inspection

	preparation, SHE) **Merck Leadership:** • Demonstrates Ethics & Integrity • Drive Results • Focus on Customers & Patients • Make Rapid Disciplined Decisions • Act with Courage & Candor • Build Talent • Foster Collaboration **Professional and Functional Competencies:** • Refer to Career Map. **Personal Attributes:** • Effective communication skills Leadership skills in alignment with the Merck Leadership Standards for respective grade. Building the required operations knowledge to support the IPT and is typically focused on a subset of responsibilities. Focused on day to day execution of support activities while building the knowledge and experience to lead improvement efforts.