Job Framework:

JOB TITLE

General role information	
Job Title:	Regulatory & Compliance Specialist
Reporting to:	Regulatory & Compliance Manager
Salary Band:	TBC
Notice period:	3 Months
Career Band:	TBC
Budget Responsibility?	No
Direct Reports?	No
Client facing role?	No

Introduction:

MSI Reproductive Choices is one of the world's leading providers of sexual and reproductive healthcare. We believe that everyone should have the right to choose. From contraception to safe abortion and life-saving post-abortion care, we are committed to delivering compassionate, affordable, high-quality services for all.

Today, our organisation has over 9,000 team members working in 37 countries across the world. Our success lies in the fact that MSI teams are locally led, entrepreneurial and results-driven, and are passionate about delivering high quality, client-centered care in their own communities. As a social business, we focus on sustainable delivery, efficiency, and funding models that are built to last, so that the women and girls we serve today will have a choice in the future too.

We know that access to reproductive choice is life changing. For some, it can mean the ability to complete an education or start a career. For others, it means being able to look after the family they already have. For everyone, it means the freedom to decide their own future, creating a fairer, more equal world.

The role

The Regulatory and Compliance Specialist is part of the Global Supply Chain function. This function is a strategic activity within MSI, aimed at ensuring quality registered products are available in the territories noted in our business plans.
This role will be responsible to collaborate with and manage manufacturers to compose dossiers against the regulatory guidelines of each territory. The role is responsible to deliver against agreed timelines, the approved specifications and then reporting progress to all key stakeholders to ensure we can monitor success through KPIs.
This position will also work with MSIs 37 country programmes identifying appropriate product innovations and strategies for Social Marketing, including preparation of registration process and support in product development or sharing expert knowledge when needed.
Ensuring that other suitable complimentary products for the Social Marketing product portfolio are identified and qualified during interactions with manufacturers.

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This role will work very cross-functional and whilst the reporting line is directly to the Regulatory and Compliance Manager, there is expected to be a large amount of work associated with our Social Marketing department where time-management will be a critical aspect of the role.

Key Responsibilities

The Regulatory & Compliance Specialist will focus on the following areas:

1. **Qualifying and Approval of suppliers and core products to support Social Marketing Growth**
   - Manage and facilitate onboarding of new suppliers and core product qualification project. This will include reviewing product chemical compound structures, quality agreement specifications, pre-qualification or SRA status ratification.
   - Report project status to Global Supply Chain Director, Regulatory and Compliance Manager and the social marketing team as necessary.
2. **Management of regulatory and product registration activities to ensure timely registration of core products in line with consolidated and approved Social Marketing commitment list**
   - Project Manage external supplier(s) responsible for product registration in all applicable countries and ensure registration status, variations and actions required are disseminated to all internal and external key stakeholders.
   - Prepare country specific dossiers for all interested countries, including dossier formatting
   - Compiles and maintains regulatory documentation databases or systems.
   - Studies scientific and legal documents.
   - Develop SOPs.
   - Ensure within the registration environment that product manufacturers take greater ownership of dossier compiling and are meeting deadlines associated with the creation of such documents.
   - Analyse regulatory landscape by country. Create and implement country specific product strategies based on the above analysis which will continue to be fed into the Global Supply Chain Director and Social Marketing teams.
   - Need to understand, interpret and advise teams on regulations, guidelines, procedures and policies relating to development, registration and manufacture of new biopharmaceutical products, to expedite submission, review and approval of global applications.
   - Work closely with country programmes to define their product requirements in detail and work with the Social Marketing team to assess Market Research and ensure feasibility in the regulatory areas (including specific timelines).
   - Ensure that all artworks are compliant with local legislation

3. **Product Development Support for MSI**
   - Identify appropriate product innovations and strategies.
   - Work with Social Marketing to manage product launches.
   - Work with Product and Market Development Manager to ensure new artworks and designs are complaint with local legislation
   - Facilitate packaging / labelling & new brand projects through coordination with relevant countries to understand local requirements and consumer preferences.
   - Collaborate with Product Manager where necessary to support development of launch plans for new products.
   - Maintain centralised master lists associated with product coding structure, artwork

registration coding and design for all products in all countries.
- Work on artwork harmonisation across regions to reduce need for individual SKUs in each country.

4. **Work with and develop suppliers to improve quality standards for all core products supporting Social Marketing requirements**
- Build strong strategic relationships with Social Marketing suppliers to ensure long term profitable relationships.
- Proactively work with suppliers to address performance issues and implement improvements.
- Conduct regular appraisals and site visits and document these.
- For selected strategic suppliers, implement processes for collaborative planning and replenishment which would aide forecasting and order management.

5. **Contribute to the GDP Quality Management System to ensure MSI maintains WDA Licence**
- Ensure SOPs are followed, and deviations and Corrective and Preventative Actions (CAPAs) implemented when necessary
- Ensure product training, audits and reporting are done on time (where your input is expected)
- Manage information and actions related to returns, rejects and thus the sharing of this information to key stakeholders.

Represent the department
- Represent the regulatory function on multidisciplinary teams & projects to provide feedback on country regulations to highlight opportunities.
- Demonstrate advanced knowledge of global regulatory requirements and criteria for submission and approval.
- Leverage regulatory and technical knowledge and experience in the development of robust regulatory strategies for programs in accordance with recognized standards. Maintain relationships with key partners and stakeholders, including R&D, Quality, Local and Regional Regulatory Lines etc., to ensure alignment on regulatory strategy and serve as a technical resource for complex projects.
- Work closely with the Social Marketing team to assess forecasting data and consumption trends to advise against projected stock-outs, over stocking and help Country Programmes place appropriate orders with manufacturers.
- Drive timely completion of commitments made to regulatory authorities and suppliers.

Please note that you may also be required to carry out reasonable additional ad-hoc duties, at the request of your line manager.

Key Skills

To perform this role, it is <u>essential</u> that you have the following sklillset:
- Good understanding of local regulatory and legislative requirements (preferably with experience in Africa, Asia and Latin America)

Desirable
- Expertise in CTD/ACTD/Non-ACTD dossier preparation

Key Experience

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To perform this role, it is essential that you have the following experience:

- 5+ years in regulatory submission (In a range of therapeutical areas – reproductive health is highly desirable)
- Similarly 5+ years' experience within the regulatory environments of import/export business.
- Considerable experience in pharmaceutical manufacturing sector or similarly regulated space

Formal Education/qualification

- Educated to degree level within a Health or Medical area of specialism, or equivalent experience (essential)
- Pharmaceutical degree is highly desirable
- Project management trained or suitably qualified through experience
- Regulatory training and trained in Good Distribution / Manufacturing Practice
- Proficient in English (essential) & French (highly desirable)

Personal Attributes

We recruit talented, dynamic people with diverse backgrounds and experiences, all united by a belief in our mission and a focus on delivering measurable results. We're proud to be an equal opportunities employer and are committed to creating a fully inclusive workplace, where everyone feels able to participate and contribute meaningfully. You must be open-minded, curious, resilient, and solutions-oriented, and be committed to promoting equality, and safeguarding the welfare of team members and clients alike.

For this role, we're looking for an individual who is:

- a resilient, flexible and overly positive person
- pragmatic in their attitude with a willingness to adapt plans to changes in circumstances/direction as the strategy or feedback dictates
- actively seeking feedback on performance (both results and behaviours) from various stakeholders in the organisation with a view to continuously learning and growing
- willing to travel up to 10% of the time to geographically challenging locations
- able to work efficiently and comfortably in a diverse multinational environment
- able to work with minimal supervision to achieve the objectives of the workplan

Our Values

Mission Driven: With unwavering commitment, we exist to empower women and men to have children by choice not chance.

Client Centred: We are dedicated to our clients and work tirelessly to deliver high-quality, high-impact services that meet their individual needs.

Accountable: We are accountable for our actions and focus on results, ensuring long term sustainability and increasing the impact of the Partnership.

Courageous: We recruit and nurture talented, passionate, and brave people who have the courage to

push boundaries, make tough decisions and challenge others in line with our mission. **Resilient**: In challenging situations, we work together and support each other, adapting and learning to find solutions, whatever we're up against. **Inclusive**: We believe that diversity is a strength. We all play our part in creating a culture where every team member can thrive, feel valued and contribute meaningfully to our mission, and where all our clients feel welcome and supported.
By signing below, you indicate that you have read and agree to this job framework.

Full Name:	
Signature:	
Date:	