Cluster Patient Safety Head, UK & Ireland

Job ID
REQ-10037681
Febr. 04, 2025
Vereinigtes Königreich

Zusammenfassung

The Cluster Head (CH), in conjunction with the Country Patient Safety Head (CPSH)/Regional Head (RH), will establish and drive Patient Safety (PS) strategy and operational excellence at the cluster level. This will be done in compliance with the national and international regulations/standards/guidelines and corporate procedures, for all marketed and investigational products - drugs and medical devices - under the responsibility of all Novartis companies and divisions in this cluster. As CH, this role acts as a role model in terms of operational excellence, leadership, and stakeholder and people management at the cluster level in complex clusters with high regulatory impact and demanding health authorities. In collaboration with the RH, set functional priorities for their respective cluster and determine strategies and objectives, support on managing efficiently budget/resources with the target of increasing productivity and quality. As a key member of PS&PV in this cluster, influence global PS strategies and promote consistency and alignment between global and local PV-related processes and activities, through PV advice within and outside the department. This role will also support the cluster/regional talent development strategy by coaching and mentoring less experienced CPSH's.

About the Role

- **Leadership:** In collaboration with the RH/RM provide key leadership skills and guidance to the CPSH's in that cluster to meet the strategic vision and regulatory requirements.
- **Cluster oversight:** Acts as operational manager of the CPSH's/CPSH associates in the cluster. The cluster head will support the recruitment, selection and onboarding of the CPSH's, and when applicable, the selection of country associates for the countries of the country/cluster. Utilize robust PV operational knowledge and strong PV management expertise to support the country/cluster in defining and executing priorities, strategies and objectives in strengthening PV oversight for complex countries/cluster with a high regulatory impact and demanding health authorities. Partner with CPSH/RH to strategically solve pharmacovigilance compliance issues.
- **UK National Contact Person for Pharmacovigilance (NCPPV):** To act as the UK NCPPV as defined by MHRA requirements.
- **Deputy UK QPPV:** To deputize for the UK QPPV in times of absence for the following responsibilities:
  - Establishing and maintaining the UK Novartis PV system for medicinal products in compliance with MHRA requirements.
  - Having oversight of the safety profiles and any emerging safety concerns in relation to the medicinal products and combined medical devices for which Novartis UK holds marketing authorizations.
  - Having oversight of the quality management system for the PV system, in collaboration with the QA function.
- **Country Patient Safety Head (CPSH) UK:** Act as the CPSH for all Novartis divisions and group companies referenced in the UK/EU PSMF. CPSH may delegate the activities to a deputy (Deputy

CPSH) but the ultimate responsibility remains with the CPSH. Delegation should be clearly documented**.**

- **Management of Safety Information:** Partner with CPSH/RH to ensure oversight of the structure and performance of Novartis PV System at country/cluster level, in order to promote, maintain and improve compliance covering the following aspects Local/global Procedures; Case Processing; Expedite ICSR reporting and aggregate reporting; Cooperation and oversight of the implementation of local RMP commitments; Training of MAH personnel in relation to PV; Local Licensing agreements; Pre and post-authorisation safety studies, with appropriate PS input as required; Patient Oriented Programs (POPs), Social Media Listening and Digital Engagement Initiatives.
- **Oversight of local PV third parties working on behalf of Novartis:** Monitor and assess the performance and productivity of PV 3rd parties in line with the applicable regulations, agreements and standard operational/ working procedures in place. In collaboration with QA and Vendor Management functions, ensure corrective and/or preventive actions are implemented in case contractual commitments are not met, as applicable.
- **Oversight of local PV third parties working on behalf of Novartis:** Monitor and assess the performance and productivity of PV 3rd parties in line with the applicable regulations, agreements and standard operational/ working procedures in place. In collaboration with QA and Vendor Management functions, ensure corrective and/or preventive actions are implemented in case contractual commitments are not met, as applicable.
- **Regulatory Intelligence:** Support CPSH/Drive the impact assessment of new local pharmacovigilance-related legislation in the country/cluster and provide operational expertise and strategic support on local PV matters and impact of any changes at country/cluster and/or global levels.
- **Compliance with Local/Cluster Legislation:** Ensure the local Pharmaco-device vigilance requirements are met. Ensure Novartis tools/systems configurations are in line with the specific local/cluster requirements to guarantee that the Country Organization receives all the safety information needed to meet local legislation (National Health Authority, Ethic Committees, etc.).
- **Health Authority Requests:** In collaboration with Regulatory Affairs (RA), ensure processes are in place to answer fully and promptly any safety related requests from Local Health Authorities in the cluster; ensure alignment with CPSH/Global Line Functions/ QPPV office in all safety-related responses, as applicable.
- **Audits, Self-assessments and Inspections:** In cooperation with the QA applicable groups, manage any local Pharmaco-vigilance inspection and/or Pharmaco-device vigilance audit and proactively, cooperate in the implementation of any corrective/ preventative action as determined by auditors/ inspectors. Contribute as Pharmaco-device vigilance SME, in other internal Novartis audits and/or third-party audits, as applicable at the cluster/country level. Lead, coordinate & manager preparation for any assigned Regional Pharmacovigilance self-assessment & support the implementation of any corrective/preventative action. In alignment with the Regional Head/manager, the cluster head may either participation in a regional self-assessment as a co-auditor or conduct a cluster/country self-assessment. When applicable, exchange learning from audits and inspections within the cluster and region.
- **UK/EU QPPV-CPSH-Cluster Head:** As a senior member of UK/EU-QPPV CPSH network, proactively contribute for the continuous monitoring and awareness of any emerging safety concerns at local/cluster level affecting the safety profile of the medicinal products for which Novartis group of companies MAHs hold authorizations. Collaborate with RA in the implementation of urgent regulatory actions at country/cluster level, as required.
- **POP Governance**: Ensure the oversight of Patient Oriented Programs (POPs) at the cluster level, in line with Novartis procedures and applicable regulations/ standards/ guidelines. Act as the operational manager for the country POP Governance Manager, as applicable.
- **Budget Management**: Reviews budget at the country/cluster level and authorizes expense reports in accordance with company guidelines.

This role offers hybrid working, requiring 3 days per week in our White City, London office.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together?: https://www.novartis.com/about/strategy/people-and-culture

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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

Abteilung
Development
Business Unit
Innovative Medicines
Ort
Vereinigtes Königreich
Website
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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representative of the patients and communities we serve.

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