Quality Assurance Expert

Job ID
REQ-10091237

十一月 10, 2026

Italy

Na voljo v: Sloven š č ina Deutsch | English | Espa ñ ol | Fran ç ais | Italiano | 日本語 | Nederlands | P y c c | Türkçe | 中文

摘要

Upravlja vidike kakovosti in projekte na podro č ju odgovornosti.
Zagotavlja in podpira splo š no skladnost GxP in skladnost s sistemi upravljanja kakovosti Novartis

About the Role

Major Accountabilities

-Zagotovite, da bodo zahteve za spremembo urejene v skladu s protokolom Novartis SOP od prejema, do izvedbe in zaklju č ka.
-Opravite spremljanje GxP na vseh oddelkih, izvedite preiskavo kakovosti glede neskladnosti, spremljajte korektivne ukrepe. Arhiviranje relativnih dokumentov.

-Koordiniranje izvajanja sistema kakovosti in postopkov za izvajanje priro č nika kakovosti Novartis in sporazumov o kakovosti.
-Zagotoviti, da bodo vsi vidiki ravnanja in distribucije farmacevtskih izdelkov v dr ž avi skladni z zahtevami priro č nika in pravilnikov o kakovosti Novartisa ter izpolnjevanje vseh ustreznih regulativnih in zakonodajnih zahtev cGMP.
-Zagotoviti, da obstaja vzpostavljen lokalni sistem kakovosti in standardni operativni postopki za vse dejavnosti, povezanih s cGMP / BDP, in da se z usposabljanjem in notranjimi revizijami ohranja skladnost s predpisi o cGMP / BDP.
-Ohranjanje trenutnega znanja o lokalnih in mednarodnih zakonodajnih in zakonodajnih zahtevah in trendih, da bi zagotovili, da bo dr ž ava nudila tehni č no podporo v vseh zadevah povezanih s kakovostjo.
-Vzpostavanje dobrih delovnih odnosov z oddelki za upravljanje dobavne verige (SCM), DRA in medicinskimi oddelki.
-Zagotovite, da se usklajeni stiki vzdr ž ujejo z regulativnimi organi, lokalnimi partnerji (dobavitelji, tretjimi strankami, dajalci licenc in distributerji) in z globalnim zagotavljanjem kakovosti.
-Zagotovite, da se pred vstopom na trg pregledajo vsa zdravila, ki prihajajo v skladu s trenutno veljavnimi postopki, registriranimi specifikacijami in lokalnimi / mednarodnimi predpisi.
-Zagotovite, da je vzpostavljen u č inkovit postopek nadzora sprememb.
-Upravljajte s prito ž bami, reklamacijami, ponaredki in posegi v skladu z Novartisovim priro č nikom o kakovosti podjetja in lokalnimi pisnimi postopki. Podpirajte / sodelujte v primerih NEM, č e je potrebno.
-Poro č anje o tehni č nih prito ž bah / ne ž elenih dogodkih / scenarijih posebnih primerov, povezanih z Novartis izdelki v roku 24 ur po prejemu
-Distribucija vzorcev tr ž enja (kjer je primerno)

Key Performance Indicators

Upravlja vidike kakovosti in projekte na podro č ju odgovornosti.
Zagotavlja in podpira splo š no skladnost GxP in skladnost s sistemi upravljanja kakovosti Novartis

Work Experience

Vodenje operacij in izvr š evanje
Sodelovanje v prostovoljnih projektih/projektih skupnosti
Funkcionalna š irina
Sodelovanje prek meja

Skills

Qa (zagotavljanje kakovosti)
Nadzor kakovosti
Uredba
Smernica
Poznavanje Capa
Dobra dokumentacijska praksa
Odpravljanje dvoumnosti
Samozavedanje
Stalno u č enje
Tehnolo š ko strokovno znanje

Language

Angle š č ina

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

Benefits and Rewards: Learn about all the ways we 'll help you thrive personally and professionally. Read our handbook (PDF 30 MB)

Primary location salary range
€ 29,800.00 - € 55,300.00

部门
Operations

Business Unit
Quality

地点
Italy

站点
Saluggia

Company / Legal Entity
IT58 (FCRS = IT058) Advanced Accelerator Applications Italy Srl

Functional Area
Quality

Job Type
Full time

Employment Type
Za č asni sodelavec (za dolo č en č as)

Shift Work
No

var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId: "kalturaplayer6af39b07abfa5887632542", provider: { widgetId: "10m7rm1pm", partnerId: "2076321", uiConfId: "55802022" }, playback: { autoplay: false, autopause: false, muted: false, loop: false }, sources: { options: {}, startTime: 0 }, disableUserCache: "true", plugins: {}, sources: { options: {}, startTime: 0 }, ui: { showCCButton: false, settings: { showQualityMenu: true, showSpeedMenu: false }, components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [{ presets: ['Playback', 'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get: kPlayer.ui.components.Remove }] } }; // Check and add plugins only if they exist if (kPlayer.plugins["download"]) { config.plugins.download = { disable: true }; } if (kPlayer.plugins["transcript"]) { config.plugins["playkit-js-transcript"] = { position: "right", // Default: bottom;('left', 'right', 'top', 'bottom') to enable transcript. expandMode: "over", // Default: alongside;('alongside', 'hidden', 'over') expandOnFirstPlay: false, showTime: true, downloadDisabled: false, printDisabled: false, disable: true }; } if (kPlayer.plugins["preventSeek"]) { config.plugins.preventSeek = { preventSeekForward: false, preventSeek: false }; } config.plugins.floating = { disable: true }; if (kPlayer.plugins["navigation"]) { config.plugins.navigation = { position: "right", expandMode: "over", expandOnFirstPlay: false, visible: false }; } if (kPlayer.plugins["hotspots"]) { config.plugins['playkit-js-hotspots'] = { disable: true }; } if (kPlayer.plugins["moderation"]) { config.plugins['playkit-js-moderation'] = { disable: true }; } if (kPlayer.plugins["info"]) { config.plugins['playkit-js-info'] = { disable: true }; } if (kPlayer.plugins["share"]) { config.plugins.share = { disable: true }; } config.ui.uiComponents = []; if (kPlayer.plugins["googleAnalytics"]) { config.plugins.googleTagManager = {}; config.plugins.googleTagManager.customEventsTracking = {}; config.plugins.googleTagManager.containerId = 'GTM-57RJQ5'; config.plugins.googleTagManager.customEventsTracking.custom = []; config.plugins.googleTagManager.customEventsTracking = { preset: { coreEvents: true, UIEvents: false, playlistEvents: false, castEvents: false } }; }

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console.error(e.message) }

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