Quality Assurance Release Officer

Job ID
REQ-10090587

十月 30, 2026

Spain

Mevcut: T ü rk | Deutsch | English | Espa ñ ol | Fran ç ais | Italiano | 日本語 | Nederlands | P y c c к и й Sloven š č ina | 中文

摘要

Sorumluluk alan ı ndaki kalite y ö nlerini ve projelerini y ö netir.
Genel GxP uygunlu ğ u ve Novartis Kalite Y ö netim Sistemlerine Uyumu sa ğ lar ve destekler

About the Role

Major Accountabilities

De ğ i ş iklik taleplerinin al ı nma an ı ndan uygulama ve kapatma an ı na kadar Novartis SOP'lerine uygun ş ekilde y ö netilmesini sa ğ lamak.
T ü m b ö l ü mlerde GxP izlemesi ger ç ekle ş tirmek, uygunsuzluk i ç in QA ara ş t ı rmas ı yapmak, d ü ze eylemleri izlemek. G ö reli dok ü manlar ı ar ş ivlemek.

-Novartis Kalite K ı lavuzu ve kalite anla ş malar ı n ı n uygulanmas ı i ç in kalite sisteminin ve prosed ü rlerinin uygulanmas ı n ı koordine etmek.
-Ü lkede farmas ö tik ü r ü nlerin kullan ı m ı ve da ğ ı t ı m ı n ı n t ü m y ö nlerinin, Novartis Kalite K ı lav Politikalar ı n ı n gerekliliklerine uygun oldu ğ undan ve ilgili t ü m cGMP d ü zenleme ve mevzuat gerekliliklerini kar ş ı lad ı ğ ı ndan emin olmak.
-T ü m cGMP/GDP ile ilgili faaliyetler i ç in yerel bir Kalite Sisteminin ve Standart İ ş letim Prosed ü rlerinin mevcut oldu ğ undan ve e ğ itim ve i ç denetimler yoluyla cGMP/GDP d ü zenlemelerine riayet edildi ğ inden emin olmak.
-Ü lkeye kalite ile ilgili t ü m konularda teknik deste ğ in verilmesini sa ğ lamak i ç in yerel ve uluslararas ı d ü zenleyici ve yasal gereklilikler ve trendler hakk ı ndaki mevcut bilgi birikimini s ü rd ü rmek.
-Tedarik Zinciri Y ö netimi (SCM), DRA ve T ı p departmanlar ı yla iyi bir ç al ı ş ma ili ş kisi kurmak.
-Mevzuat Otoriteleri, yerel ortaklar (tedarik ç iler, ü ç ü nc ü taraflar, ruhsat sahipleri ve distrib ü t ö rler) ve K ü resel Kalite G ü vence ile koordineli bir temas ı n s ü rd ü r ü ld ü ğ ü nden emin olmak.
-T ü m gelen ila ç ü r ü nlerinin piyasaya serbest b ı rak ı lmadan ö nce ge ç erli prosed ü rlere, tescilli spesifikasyonlara ve yerel/uluslararas ı d ü zenlemelere uygun ş ekilde denetlenmesini sa ğ lamak.
-Ge ç erli bir De ğ i ş im Kontrol s ü recinin bulundu ğ undan emin olmak.
-Novartis Kurumsal Kalite K ı lavuzuna ve yerel yaz ı l ı prosed ü rlere g ö re ş ikayetleri, geri ç a ğ ı rmal taklitleri ve onays ı z ü r ü n de ğ i ş iklikleri y ö netmek. Gerekti ğ i ş ekilde NEM vakalar ı n ı desteklemek bunlara kat ı lmak.
-Novartis ü r ü nleriyle ilgili teknik ş ikayetlerin / olumsuz olaylar ı n / ö zel durum senaryolar ı n ı n al ı nd ı ktan sonraki 24 saat i ç inde raporlenmesi
-Pazarlama ö rneklerinin da ğ ı t ı m ı (uygun oldu ğ unda)

Key Performance Indicators

-Sorumluluk alan ı ndaki kalite y ö nlerini ve projelerini y ö netir.
Genel GxP uygunlu ğ u ve Novartis Kalite Y ö netim Sistemlerine Uyumu sa ğ lar ve destekler

Work Experience

-Operasyon Y ö netimi ve Uygulama
-G ö n ü ll ü ve sosyal sorumluluk projelerine kat ı lmak
-Fonksiyonel Kapsam
-S ı n ı r ö tesi i ş birli ğ i

Skills

-QA (Kalite G ü vencesi)
-Kalite Y ö netimi
-Đ ü zenleme
-Kural
-Ç apa Bilgisi
-İ yi Dok ü mantasyon Uygulamas ı
-Belirsizlikle Ba ş a Ç ı kmak
-Ö z Fark ı ndal ı k
-S ü rekli Ö ğ renme
-Teknolojik Uzmanl ı k

Language

İ ngilizce

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
€ 34,700.00 - € 64,400.00

部门
Operations

Business Unit
Quality

地点
Spain

站点
Barcelona Gran V í a

Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmac é utica, S.A.

Functional Area
Quality

Job Type
Full time

Employment Type
Kadrolu

Shift Work
No

var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId: "kalturaplayer6ae734dad7d73143759319", 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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