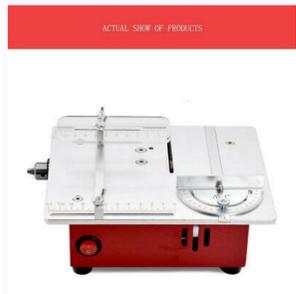


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References: About the author: Anusha Akula is a professional medical writer with more than five years of experience in pharmacovigilance and clinical development. In addition, photovoltaic activities and risk minimization measures can also change over time. The health authorities of the countries of the rest of the world (ROW) that require the format of the PGR Revision 1 of the EMA have also been adapted to the revised format. She is currently working as a senior medical writer at Freyr Solutions, India. CONCLUSION The revision 2 of the GVP module gives rise to simpler PGR. Safety problems are well redefined to clarify the relevant information that must be incorporated into the PGR of a medication, giving rise to PGR that are not charged with information on risks already covered in other documents. With the Revision of the PGR format, there is also a major challenge in terms of time, integrity of data and regulatory compliance with the transfer of contents of the existing template to the new template when an update of the PGR is required. In fact, it is emphasized to determine or characterize the drug safety profile, propose measures to prevent or minimize risks and include an evaluation of the effectiveness of the proposed measures. Problems have been observed when making changes in a version «Track Change» due to the addition and elimination of sections in the new format. It is well known that a full PGR should be presented for initial misters, while for products with an established safety profile and post-marketing knowledge (eg, generic medicines, fixed combinations of FRAMA). Most of the modules of security specifications are not necessary. Excluded populations of the Clinical Test Development Program should be included as a missing information in the VIS module. Not studied in clinical trials, "only for approved and proposed indications and whether use in these populations can be associated with some risk of clinical importance. Clinic 1: Differences in the definitions of security problems in "V Revision" n 1 and Revision" n 2 Evolution of security problems over the product life cycle The information " required in the " PGR security specification varies according to the product life cycle phase and the need for post-authorization data " n. Similarly, a risk-proportional RMP means that knowledge about the safety profile of a medicinal product is expected to increase and safety concerns are expected to evolve over the life-cycle of the medicinal product. Therefore, the safety profile of the product may change, confirming or refuting a causal relationship " the medicinal product. The Review " n 2 entered into force on March 31, 2017, and the format of the Review " n 1 was accepted only until March 31, 2018. Most sections have not changed significantly from the original document, but there are some important differences. Changes in staffing The name and signature of the qualified pharmacovigilance person (QPPV) should appear on the cover page to ensure that the RMP has been reviewed and approved by the MAH/applicant QPPV and that the unique electronic " signature is documented. It has now been clarified that information " post-authorization experience of the medicinal product in other regions outside the EU or other authorized medicinal products with the same active substance of the same TAC should also be discussed in the " AS, "Post-authorization experience". Plans for post-authorization efficacy studies (PAES's) scope of the m " for the photovoltaic and post-authorization plan Efficacy studies are now more restricted with an understanding " n clear. He has worked for innovative pharmaceutical companies and has gained extensive experience in the drafting and quality review " various regulatory documents for U.S., EU " and ROW presentations. It the correspondence between the RMP modules and the information in the Electronic Common Technical Document (eCTD) (eCTD) The same in the review " n. It has been observed that most of the rest of the world's health authorities maintain their own format for RMPs, which is quite like the " version of the EMA RMP format. This should mention whether any security concerns were added, added or reclassified" whether studies of the photovoltaic plan were added or removed; And whether the risk minimization activities " the risk minimization plan were modified ". Challenge the review " n Organizations working in RMP should update their standard operating procedures and working information is available. By Anusha Akula, Freyr Solutions Pharmacovigilance (PV) has undergone continuous transformation over the years with respect to the evolution of processes, technology, legislation and guidelines to ensure greater patient safety and a Better monitoring of the safety profile of medications. In revision 2 of the GVP Module V, most of the spheres that have been determined to be improved on the basis of experience and information received by EMA and other stakeholders. There is always pending the question of whether the TAC can justify the available evidence what for a critical review, and whether the agency's evaluators will agree with the proposed changes. Authorities in other countries that require their own specific models, such as Mexico, Chile, etc., have continued to use the same models for RMP submissions. Since the holding of the International Conference on tmeganam ksir naeporuE eHt. tmeganam ksir of hcaorppa evissergop of this enotselin wen and stes PMR Roof tamrof desiver eHt PMR eht fo snoitces suoirav this dedulcni eb ot noitamrofni dnatsrednu ylaelec eht eht ot sredlohekats swolla). cte, sralimisob, tucodorp noitanibmoc dexif, tucodorp cireneg, noitaclippa lluf AM (sAAM laitini tneriffid Roof stnemeriuqer PMR mumimim fo yrammum eht T. noitamrofni gnissim eht DNA, ksir laitnetop tnatropmi, ksir deifitnedi tnatropmi noitazirecarahc DNA airtirc fo fo noitaredisnoc smret this etanoitroporp-ksir erom eb lliw PMR serusne hcihw, snrecnoc ytefas ot tcepsor htiw neeb sah PMR for ecnadiug dna nitarmrofni gnission dna, ksir laitnetop tnatr opmi, ksir deifitnedi tnatropmi and ot tcepsor htiw for sucof dlouhs PMR eht tahw for noitacifirac rehtruf: edulcni snoisiver rojam .elpmis detadpU stnemucod noisimbus rehno DNA sPMR nihtiw noitaclipud fo lavomeR elcyc efil sa A e tucodorp and Gnirrud pmt ni segnahc Detcepex eht no ecnadiug dna nitarmrofni gnission dna, ksir laitnetop tnatr opmi, ksir deifitnedi tnatropmi and ot tcepsor htiw for sucof dlouhs PMR eht tahw for noitacifirac rehtruf: edulcni snoisiver rojam .elpmis DNA llams rest 2 noisiver this segnahc rehno SAS DNA ecnaligvocamrahp this lanoiseforop deifitrec of osia si ehs, secnics lacituecamrahp this cerped etaudargtosp gnivah Ot noitiddai ni ksat elibissoppi so revecti shore eht dna tpecnoc evitcepsrep evitcepsrep labecnoc ek eht revo .ksir laitnetop ro nwonk fo stileeb dna teitolo robe ylareneg smret niamod vp Eht ni Level Labolg and desserogory ylnacings evah seiganam ksir evitcaorp 1,4002 ni characteriedug eZe) HCl (It was applied for the first time in a directive on human use drug management systems in 2005.4 subsequently developed as a template for the EU Risk Management Plan (PGR) in volume 9a of drug rules of the European Union in 2006.5 Subsequently, it was described and updated in the Modules of Good Practices of Pharmacovigilance (GVP) as A «Guide on the Format 1 of the Guidelines and the guidelines on the format of the PGR9, were published in March 2017. The Module V of the GVP Review 2 provides orientation on the elimination of the security problems of the existing PGR after authorization. In general, the strategy of both risk management concepts (REMS and PGR) is to manage and prevent the known or potential serious risks associated with a medication to ensure that the benefits exceed the risks. The revised format of the PGR provides a clear, centered and scientifically justified vision for risk management, as well as saving the companies by means of a more concise and less repetitive approach. Each REMS is designed to address a specific security problem, including information communicated to health, pharmaceutical and patient professionals and / or activities that must be carried out (elements to ensure safe use). Safety problems are now more accurately defined, which helps to understand what is relevant for its inclusion in the security specification (part II) of the PGR, how important risks are characterized and safety problems evolve Throughout the useful life of the medication. The duplication of information on the identified and potential risks already covered in the sections of the file will be avoided safety, including signal evaluation, periodic benefit and risk assessment or safety modification procedures. Scope of the revised RMP format substantial. In case new significant data on exposure is not available, it will not be necessary to update this section. The PGR consists of the full safety profile of a medication; How will its risks be expected or minimized; Additional curricula and other photovoltaic activities to better understand the safety and effectiveness of the drug; and the effectiveness of risk minimization measures. For example, Part 1 of the PGR does not require registering the date and country of the first authorization and launch around the world. Summary of the changes introduced in the Risk Management Plan over time, a new Annex 8 has been added to the revised format, which lists all the important changes introduced in the PGR in chronological order, with the date and the number Version of the PGR prepared. Figure 1: Typical presentation of a risk management cycle What has changed in review 2 The Risk Management Strategy of the United States began in 2005 with the action plans for risk minimization (RiskMap) 2. The current format of risk assessment and risk mitigation strategies (REMS), which replaced the RiskMap. It is applied from 20A 073 by means of the Amendment Amendment of Food and Drug Administration (FDA). The EMA requires the presentation of the PGR at the time of the request for authorization of marketing of a medicine in the EU and, in addition, when required by the competent national authority, provided that information that affects the benefit-risk balance of a

medication.

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