|  |  |  |
| --- | --- | --- |
| **Schlüsselwörter** | Arzneimittelrisiko; Zuständigkeit; Maßnahmen | |
| **zugrunde liegendes Qualitätsdokument** | VAW 121111 „Rapid-Alert-Meldungen der Klassen I und II (RA I, RA II); Rückrufe “ | |
| **Querverweise, Bezug** | VAW 121111; Kap. 3.2 | |
|  | |  |
| **fachlich geprüft** | Alexander Kammerlocher | 18.01.2023 |
| **formell geprüft** | Dr. Katrin Reder-Christ | 06.02.2023 |
| **CoUP-Vorgabe** | Ja  Nein | |
| **Pflichtformular** | Ja  Nein | |
|  | Compilation of Union Procedures on Inspections and Exchange of Information (EMA/224865/2022 Rev 18 Corr.):  Procedure for managing rapid alerts arising from quality defects risk assessment (Appendix 3) | |
|  | |  |
| **im QS-System gültig ab** |  | 06.02.2023 |
| **in Kraft gesetzt** |  |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Follow-up and Non-urgent Information for Quality Defects** | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |
| **Sender:**  <add letter head of sender> | | | | | | | | | **1. National Reference no.:**  (when applicable) | | | | | |  | |
| **2. Recall no. assigned:** | | | | | |  | |
| **3. To:** | | | BfArM | | | BVL | | PEI | | | OLGB | | | | | OLVET |
| **4. Files attached?** | | | | | <please choose> | | |  | | | | | | | | |
|  | **5. Product** | | | | | | **6. Strength** | | | | | | **7. INN or Generic name** | | | |
| <text> | | | | | | <text> | | | | | | <text> | | | |
| **8. Brand/Trade name** | | | | | | **9. Dosage form** | | | | | | **10. Marketing authorisation number** | | | |
| <text> | | | | | | <please choose>  <text> | | | | | | <text> | | | |
| **11. Batch number(s) and bulk** (if different) | | | | | | | | | | | | | | | |
| <text> | | | | | | | | | | | | |  | | |
| **12. Marketing authorisation holder** | | | | | | | | | **13. Manufacturer** | | | | | | | |
| **Name** | | <text> | | | | | | | **Name** | <text> | | | | | | |
| **Address** | | <text> | | | | | | | **Address** | <text> | | | | | | |
| **E-mail** | | <text> | | | | | | | **E-mail** | <text> | | | | | | |
| **Phone** | | <text> | | | | | | | **Phone** | <text> | | | | | | |
| **14. Subject title** | | | | | | | | | | | | | | | | |
| <text> | | | | | | | | | | | | | | | | |
| **15. Issuing authority** | | | | | | | | | | | | | | | | |
| **From (issuing authority)** | | | | <text> <text> | | | | | **Phone** | | | <text> | | | | |
| **Contact person** | | | | <text> | | | | | **E-mail** | | | <text> | | | | |
| **Signature** | | | |  | | | | |  | | |  | | | | |
| **16. Date/Time** | | | | <dd.mm.yyyy/hour.minutes> | | | | | | | | | | | | |

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