|  |  |
| --- | --- |
| **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** | [x]  Ja [ ]  Nein |
| **Pflichtformular** | [x]  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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