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Abbreviations

ANSM	Agence Nationale de Sécurité du Médicament et des produits de santé
CAPA	Corrective Action and Preventive Action
DHPC	Direct Healthcare Professional Communications
E2B	Format for Data Elements for transmission of Individual Case Safety Report
EMA	European Medicines Agency
EU QPPV	European Qualified Person for Pharmacovigilance
EV	EudraVigilance database
GVP	Good Pharmacovigilance Practices
ICSR	Individual Case Safety Report
INN	International Non-proprietary Name
MAH	Marketing Authorisation Holder
MLM	Medical Literature Monitoring
NCA	National Competent Authority
MedDRA	Medical Dictionary for Regulatory Activities
PBRER	Periodic Risk Benefit Evaluation Report
PIL	Product Information Leaflet
PSMF	Pharmacovigilance System Master File
PSUR	Periodic Safety Update Report
PV	PharmacoVigilance
Q&A	Question and Answer
RMP	Risk Management Plan
SmPC	Summary of Product Characteristics
XML	Format of the file for transmission eXtensible Markup Language

1. Qualified person responsible for pharmacovigilance (QPPV)
1.1 Description of the responsibilities guaranteeing that the QPPV has sufficient authority over the pharmacovigilance system
As per Module I of Good Pharmacovigilance Practices in force, the QPPV handles several responsibilities:

- Establishment and maintenance of the marketing authorization holder's marketing system;
- Promote maintain and improve compliance with the legal requirements;
- Having an overview of medicinal product safety profiles and any emerging safety concerns;
- Being aware of any conditions or obligations adopted as part of the marketing authorisations and other commitments relating to safety or the safe use of the products;
- Being aware of the risk minimisation measures;
- Being aware of and having sufficient authority over the content of risk management plans;
- Being involved in the review and sign-off of protocols of post-authorisation safety studies conducted in the EU or pursuant to a risk management plan agreed in the EU;
- Being aware of post-authorisation safety studies requested by a competent authority including the results of such studies;
- Ensuring the conduct of pharmacovigilance and the submission of all pharmacovigilance-related documents in accordance with the legal requirements and GVP;
- Ensuring the necessary quality, including the accuracy and completeness, of pharmacovigilance data submitted to the competent authorities in Members States and the Agency;
- Ensuring a full and prompt response to any request from the competent authorities in Members States and from the Agency for the provision of additional information necessary for the benefit/risk evaluation of a medicinal product;
- Providing any other information relevant to the benefit-risk evaluation to the competent authorities in Members States and the Agency;
- Providing input on the preparation of regulatory action in response to emerging safety concerns (e.g. variations, urgent safety restrictions, and communication to patients and healthcare professionals);
- Acting as a single pharmacovigilance contact point for the competent authorities in Member States and the Agency on a 24-hour basis as well as a contact point for pharmacovigilance inspections.

This responsibility for the pharmacovigilance system means that the QPPV has oversight over the functioning of the system in all relevant aspects, including its quality system (e.g. standard operating procedures, contractual arrangements, database operations, compliance data regarding quality, completeness and timeliness of expedited reporting and submission of periodic safety update reports, audit reports and training of personnel in relation to pharmacovigilance).
Specifically, for the adverse reaction database, the QPPV is aware of the validation status of the database, including any failures that occurred during validation and the corrective actions that have been taken to address the failures. The QPPV is also informed of significant changes that are made to the database (e.g. changes that could have an impact on pharmacovigilance activities).
The QPPV may delegate specific tasks, under supervision, to appropriate qualified and trained individuals, for example, acting as safety experts for certain products, provided that the QPPV maintains system oversight and overview of the safety profiles of all products. Such delegation is documented. In addition, the QPPV ensures that all the staff involved in pharmacovigilance activities have received appropriate training.
They have the support of medically qualified staff for medical evaluations.
The procedure describing these responsibilities is PR-VIG-UM-003 "Procédure sur la fonction QPPV".
TEST QO - test édition
1.2 QPPV Summary Curriculum vitae
Sandrine BOUCHENOT, is employed by Universal Medica and appointed by Laboratoires CRINEX as its European Qualified Person for Pharmacovigilance (EU QPPV) for the products listed in Annex H.
With her extensive experience in the pharmacovigilance field, she has acquired adequate theoretical and practical knowledge for the performance of pharmacovigilance activities.
[First Name and Last Name]

[Full Address]

[Phone Number]

[Email]

OBJECTIVE

Mention the type of role you are seeking with brief details about your years of experience, education and impressive work accomplishments related to the job you're applying to.

SUMMARY OF SKILLS

Include unique, marketable skills related to the job you want
Include any additional work accomplishments that show initiative and accountability
Choose specific experiences to showcase employable skill sets
Use as many keywords from the job description as possible

WORK EXPERIENCE

Job Title, Company, City, State, Dates of Employment

Describe your job responsibilities as accomplishments
Begin sentences with verbs
Use keywords from the job description
List jobs from most recent to least recent
EDUCATION

[College Name, City, State, Years of Attendance]

VOLUNTEER EXPERIENCE

Only include volunteer experience if it directly relates to the job you are applying to

REFERENCES

Available upon request
her curriculum vitae and proof of registration with the EudraVigilance database are provided in Annex A.
1.3 Contact details
Sandrine BOUCHENOT
Universal Medica
13 rue Henri Matisse, 77 000 La Rochette
Tel: (01) 64 79 54 13
Mobil: (06) 08 28 52 11
Fax: (01) 64 79 54 13
E-mail: sandrine.bouchenot@universalmedica.com

The QPPV can be joined at test the clock / 7 days a week.
1.4 Back-up arrangement
Sandrine BOUCHENOT is responsible for the EU QPPV and RPV FR functions.
Note Universal Medica : Dans le cas où UM assure la fonction EU QPPV intérimaire mettre le texte suivant, sinon décrire le processus client.

In the absence of the QPPV, the person who assure the interim function is designated.

A calendar of QPPV permanence is built and approved. Approved changes are implemented as necessary. The Deputy QPPV has the skills and resources needed and accepts responsibility for the function.

For the absences of the QPPV:

- A mission email is sent to the Deputy QPPV before a planned absence and in the shortest possible time in case of unscheduled absence. This email contains instructions on the tasks to be conducted during the period of absence. The Deputy QPPV acknowledges receipt.
- At the end of the mission, the Deputy QPPV sends the results of his actions during the replacement period, by email, to the QPPV, who acknowledges receipt.
- All of these elements are documented and stored.
- The Chief Pharmaceutical Officer is informed as well as other Deputy QPPV.

XXXXXX TEST QO XXXXXXX

1.5 Local person for Pharmacovigilance

Details about the contact person for pharmacovigilance nominated at a national level, as well as her responsibilities and tasks can be found in Appendix A.

2. Organisational structure of the marketing authorisation holder
2.1 Description of the marketing authorisation holder organisational structure
Laboratoires CRINEX has headquartered which is located 1 bis René Anjolvy 94 250 GENTILLY and has currently no affiliate. It is a Marketing Authorization (MA) holder and/or a distributor in charge of marketing of medicinal products.
A diagram showing the organization of pharmacovigilance of Laboratoires CRINEX is available below.

2.2 Sites where Pharmacovigilance functions are undertaken
Pharmacovigilance activities are spread over test sites:

- Laboratoires CRINEX
  1 bis René Anjolvy 94 250 GENTILLY

106 Bureaux de la Colline, 92210 Saint-Cloud

- UNIVERSAL MEDICA
  56 boulevard de l'Embouchure
  31200 Toulouse
  France

13 r Henri Matisse, 77000 LA ROCHETTE

Locations of the different pharmacovigilance activities are presented below:

Activity	Location
Individual case safety report collection	UNIVERSAL MEDICA
Individual case safety report evaluation	UNIVERSAL MEDICA
Safety database case entry	UNIVERSAL MEDICA
Periodic safety update report	UNIVERSAL MEDICA
Signal detection and analysis	UNIVERSAL MEDICA
Scientific literature survey (international + local)	UNIVERSAL MEDICA
Risk management plan management	UNIVERSAL MEDICA
Pre- and post- authorization study management	UNIVERSAL MEDICA
Management of safety variations of SmPC	UNIVERSAL MEDICA

2.3 Delegated activities relating to the fulfilment of pharmacovigilance
Laboratoires CRINEX uses the services of UNIVERSAL MEDICA test its pharmacovigilance (PV) activities.
A table listing the distribution of responsibilities between Laboratoires CRINEX and UNIVERSAL MEDICA can be

found in Annex A.
Services of UNIVERSAL MEDICA cover test of Laboratoires CRINEX.Therefore, the services provided by the third party are similar to those managed by the internal PV service of a pharmaceutical company:

- the initial management of a case regardless of its source (competent authorities, health professionals, patient, literature,...) after notification of adverse events and special situations until its transmission to EudraVigilance.
- a daily review of EudraVigilance cases.
- the preparation of periodic safety update reports (PSUR) at the intervals specified by the French Code of the Public Health or other regulations, depending the market authorization,
- a weekly scientific monitoring for pharmacovigilance (MEDLINE and EMBASE),
- a local scientific monitoring for pharmacovigilance (local medical journals) published in France, and in export territories.
- a monitoring of EMA publications (MLM),
- any activity required by the function (ANSM investigation, request of other national competent authorities, EMA, etc.),
- the signal management,
- the provision of at least one certified "EudraVigilance" person

Laboratoires CRINEX is kept informed by regular reporting.
ajouter un paragraphe similaire pour les autres prestataires PV, par exemple à l'export.

Resources dedicated to Pharmacovigilance

Staff involved in the routine pharmacovigilance activities of the products concerned by this PSMF represents test full time equivalent for Laboratoires CRINEX and test full time equivalents for UNIVERSAL MEDICA.
LONGTEXT_FTE_AUTRE_PRESRARAIRES_PV
Moreover, there are other teams for literature search and quality system management.
Several collaborators at UNIVERSAL MEDICA have successfully completed the electronic reporting of ICRSs knowledge and the Extended EudraVigilance Medicinal Product Dictionary (XEVMPD) knowledge evaluation.
2.4 Links with other organisations
Technical service providers are involved in the fulfilment of pharmacovigilance obligations (list available in Annex B).
Their management is described in the procedure PR-EXM-UMG-002 "Achat et gestion des fournisseurs" for Universal Medica and in the test for Laboratoires CRINEX.
Laboratoires CRINEX markets medicinal drugs in other countries than France through third party partners (list available in Annex B).
For every new marketing agreement concerning a product of the pharmaceutical company, a SDEA (Safety Data Exchange Agreement) is established with the partner. The process to manage partners is described in the procedure PR-VIG-UM-012 "Gestion des partenaires de distribution et commercialisation" for Universal Medica and in the test for Laboratoires CRINEX.

3. Safety data sources
Safety data can reach Laboratoires CRINEX from a variety of sources. These include, but are not limited to medical information, health professionals, patients, sales representative, National Competent Authorities, other MAHs or literature.
Laboratoires CRINEX has TEXT_HAS_OR_NOT_WEBSITE.
Safety data include adverse drug reactions (ADRs) and reports related to special situations as defined in GVP Module VI and French guidelines.

Glossaries of the schema
ANSM: Agence nationale de sécurité du médicament et des produits de santé (French Health Authority)
BDB: Bibliographic Databases
CRPV: Regional Pharmacovigilance Center
EMA: European Medicines Agency
EVE: test
ICSR: Individual Case Safety Report
NCA: National Competent Authorities
UM : Universal Medica
WRL: Weekly Report of Literature
The list of parties involved in collection of ICSRs and reporting to the competent Authorities is available in Annex B.
The list of safety data associated with the description of safety data sources is available in Annex B.
The description of process for ICSRs from collection to reporting to Competent Authorities is presented below.

4. Computerised systems and databases
4.1 Pharmacovigilance Computerized Database
The pharmacovigilance database, test, is held by UNIVERSAL MEDICA.
This database is used to receive, collecte, and record safety information.
This PV database is compliant with the internationally agreed standards for electronic submission of adverse reaction reports (ICH E2B).
Any case entered in this database is coded with the latest version of the Medical Dictionary for Regulatory Activities (MedDRA).
Health data relating to test are hosted by Claranet which has been granted a license for this purpose by the Health Ministry.
Data backup process id performed by GRITA. GRITA operates a backup media platform (LTO cartridge) for fast backup, restore and transfer data eVeDrug's applications and programs. There is a daily backup of database on Backup platform hosted in the Télécity data center. According to the requirements of the Health Data Host, at least one annual restoration test is carried out. At each modification of program, a backup is performed on external hard drive. All copied source codes are dated
The pharmacovigilance database test has been initially validated on DD-MMM-YYYY (QI/OQ/QP validation) and complies with ICH, E2B regulation, EMA and FDA guidelines:

- XML files can be generated and can be imported in the EudraVigilance database (via EVWEB, Web Trader then local import);
- Audited records can be generated and any record can be readily retrieved;
- Only authorized access to records and/or process is permitted to qualified and trained individuals (user name and password);
- Appropriate audit trail is generated, retained and auditable;
- Documentation is controlled;
- No falsification and respect of confidentiality
- Multisite copies, back-up procedure, under the editor responsibility.

It was upgraded to version xxx released on DD-MMM-YYYY. The application is maintained at the validated state by UNIVERSAL MEDICA. Concerning the change control, UNIVERSAL MEDICA is responsible to realize the tests and make available the documentation (results of tests, change control form). UNIVERSAL MEDICA analyses the impact of the changes on its process, quality documentation and training then handle the defined actions in a second time.
test access is restricted to duly trained Laboratoires CRINEX and UNIVERSAL MEDICA collaborators. Each collaborator has personal and untransferable login and password, which gives him/her a level of access that matches his/her needs. The access levels are: user-reader only (no modification possible, consultation only), user (data entry) and administrator (all permissions).
The EU QPPV has a permanent access to this database.
The management of the safety database is described in the procedure PR-VIG-UM-017 "Gestion des bases de données en Pharmacovigilance" and in the test for Laboratoires CRINEX.
4.2 Computerised data management
Laboratoires CRINEX
Décrire le système informatique du client
UNIVERSAL MEDICA
Access to the server requires username and password. Their security is ensured by following measures: staff commitment to confidentiality, access code with password protection on all workstations, restricted access to folders only to the allowed collaborator, antivirus protection.
Each station is equipped with an automatic update anti-virus. Servers computer are stored in a specific room with a restricted access (pass) protected against accidental water damages.
UNIVERSAL MEDICA is running a Dell PowerEdge server system at its premises in Saint-Cloud that includes a RAID5 storage system (i.e. high redundancy of all stored data and no loss of data if one hard disk crashes).
Except form planned down time for service, the system is available 24/7.
All applications and current project data are stored in this system. Archiving of electronic data is continuously performed according to a predefined back-up rotation scheme.
Non-current data are permanently stored on duplicate optical devices which are kept at two different fire protected places.
4.3 Paper data management

Laboratoires CRINEX
Décrire la gestion de la documentation papier du client

UNIVERSAL MEDICA
Paper documents or client files are stored in a fireproof waterproof key closed cabinet. A fire extinguisher is available to staff in the event of fire.

Original paper documents are scanned, stored electronically in a single file organized by customer.

5. Pharmacovigilance processes
5.1 Task and responsibilities for Pharmacovigilance processes
Different pharmacovigilance tasks are handled by UNIVERSAL MEDICA on behalf of Laboratoires CRINEX (Annex A). For each task performed, procedures, manuals or working instructions describe the different steps to be followed, defined the person in charge and detail the system in place that supports appropriate and timely decision making and action.
A complete list of the procedures in force at Laboratoires CRINEX and UNIVERSAL MEDICA concerning the handling of pharmacovigilance tasks is attached in Annex E.
5.2 ICSR collection, collation, follow-up, assessment and reporting
The distribution of tasks and responsibilities related to this process is detailed in the distribution table of activities between and UNIVERSAL MEDICA in Annex A
Procedures and working instructions describing the processes are:

Laboratoires CRINEX:

- Nom du document 1
- Nom du document 1

Laboratoires CRINEX:

- PR-VIG-UM-001 Pharmacovigilance Cases Management
- PR-VIG-UM-002 Imputabilité en Pharmacovigilance
- PR-VIG-UM-005 Veille bibliographique en pharmacovigilance
- PR-VIG-UM-006 EudraVigilance management on behalf of a client
- PR-VIG-UM-009 Electronic transmission of ICSR via EV WEB
- PR-VIG-UM-016 Gestion d'un usage non conforme
- WI-VIG-UM-001 Modalités pratiques de veille en pharmacovigilance dans les revues papiers et les bases de données
- WI-VIG-UM-004 Management of EudraVigilance Monitoring
- WI-VIG-UM-007 Electronic transmission of ICSRs to EudraVigilance
- WI-VIG-……-001 (Mode opératoire client)

5.2.1 Collection

The collection point of ICSRs are Laboratoires CRINEX and UNIVERSAL MEDICA. ICSRs can reach from a variety of sources. These include,

- Spontaneous reports from Health Professionals or paramedics,
- Spontaneous reports from consumers or non-Health Professionals,
- Reports from sales representatives,
- Reports from EudraVigilance,
- Reports from literature.

Notifications are communicated to UNIVERSAL MEDICA by phone call, fax, letters, e-mails.

When they become aware of an adverse event or pharmacovigilance information, Sales Representatives (Involved in the Drug Promotion) shall transmit immediately the alert to Laboratoires CRINEX.

Cases reported from EudraVigilance, literature or from MLM service (EMA) are captured by UNIVERSAL MEDICA through weekly surveillance.
For all cases, UNIVERSAL MEDICA should collect the 4 criteria to have a valid case. If a patient reports directly pharmacovigilance information, UNIVERSAL MEDICA invites the patient to communicate his Health Professional contact information.

Management of call:
During office opening hours
First line medical information enquiries will be responded by UNIVERSAL MEDICA with official documents (SmPC and PILs), the documentation transmitted and validated by Laboratoires CRINEX (Q&A) and regulatory communications (Health agencies). All first line medical information enquiries will be logged into the database Medica Source and will be recorded in the Medical Information enquiries reporting. If the call is related to a PV case, the Pharmacovigilance form will be populated and immediately send via Medica Source.
If the question cannot be answered with official documents (SmPC, PILs or Q&A), the documentation transmitted and validated by Laboratoires CRINEX and regulatory communications (Health agencies), the request will be considered as a second line request. All second line medical information enquiries will be logged into the database Medica Source and will be recorded in the Medical Information enquiries reporting. Second line medical information enquiries will be transferred to Laboratoires CRINEX within the next 24 hours via Medica Source using the appropriate e-mail template. Laboratoires CRINEX is responsible for the answer.
During office opening hours, any incoming call related to pharmacovigilance received on Laboratoires CRINEX's switchboard will be directed to UNIVERSAL MEDICA. In the absence of the NAME OF THE CLIENT operator, a message on the answering machine indicates UNIVERSAL MEDICA's contact details.
Out-of-hours include:

- Week nights between 06 pm and 09 am;
- Week-ends;
- Annual leaves.

During these periods, calls are handled by UNIVERSAL MEDICA. UNIVERSAL MEDICA reports to Laboratoires CRINEX any calls received during out of hours the day after.

Every working day and every bank holiday, a line test is carried out in order to check the correct redirection of the on-call system. Every week, an e-mail is sent to trace this.
5.2.2 Management
PV cases are forwarded by Laboratoires CRINEX to UNIVERSAL MEDICA in real time.
Duplicate search
After each reception at UNIVERSAL MEDICA, before the case registration step, a duplicate search is performed by UNIVERSAL MEDICA
PV Case registration and processing
When received by UNIVERSAL MEDICA an internal case ID is linked to the case.
All signs, symptoms, diseases, diagnosis, therapeutic indications, names and qualitative results of investigations, surgical and medical procedures and medical social/family history are coded according to the latest version of MedDRA.
The narrative of the case is written by the pharmacovigilance officer according to the template used at UNIVERSAL MEDICA. The information is presented in a logical time sequence, in the chronology of the patient's experience including the clinical course, the therapeutic measures, outcome and follow-up information obtained.
PV Case approbation
A systematic approbation of ICSRs is performed by UNIVERSAL MEDICA before submission of the case to Competent Authorities.
The person in charge of the approbation reviews the consistency of the case, identifies potential missing elements and checks the language, coding and wording. A medical review is done to validate the causality assessment (imputability) and the narrative.
Closure of case
The project manager or the project coordinator at UNIVERSAL MEDICA is in charge of the closing. ICSR is closed within 15 days after submission if no additional information is expected.
The case will be re-opened in case of reception of new information.
The criteria for closure are:

- No additional information is expected for the case such as the initial reporter does not want to be contacted or does not respond after 3 attempts of follow-up for serious cases and 2 attempts for non-serious.
- Death: in the event of death of the patient, the date, cause of death, results of the autopsy (if available) will be provided.

- Case has been detected through the literature review
- Case has been detected through EudraVigilance Monitoring and no additional information is expected.

5.2.3 Submission of reports
The PV Officer at UNIVERSAL MEDICA submits all valid ICSRs to EudraVigilance in ICH-E2B format as an XML message within 15 days for serious cases and 90 days for non-serious cases via the EVWEB platform. The PV Officer at UNIVERSAL MEDICA transfers the CIOMS to the partner if applicable.
The PV Officer tracks from EudraVigilance the Acknowledgement Message (ACK) of the submission (XML format) or acknowledgement of receipt of the transfer to the partner. They are electronically saved .
5.2.4 Monitoring of the scientific and medical literature
A weekly monitoring is conducted by UNIVERSAL MEDICA:

- Medical Literature Monitoring as a service provided by EudraVigilance. The monitoring of medical literature and the entry of relevant information into EudraVigilance is carried out by EMA
- Regular literature surveillance using the:
- International bases EMBASE and MEDLINE
- Local non indexed publications in Medline and Embase.

If an adverse event or a special situation likely to be in relation with a Laboratoires CRINEX's product is detected during the review of bibliography, the article is analysed (country of origin, product of the laboratory or not) and if it is confirmed that the case is in relation with a Laboratoires CRINEX's product, the case is entered into the safety Database.
5.3 Continuous monitoring of product risk/benefit profiles
UNIVERSAL MEDICA is responsible for conducting all signal management activities for the Laboratoires CRINEX medicinal products as described in PR-VIG-UM-008 "Gestion du signal en Pharmacovigilance" (signal detection, validation, analysis and prioritisation and providing recommendations to Laboratoires CRINEX for actions) and in Laboratoires CRINEX's SOP test
Signal detection/validation for Laboratoires CRINEX is performed through several reports:

- Periodic biannually reports for drugs following several criteria.
- Periodic annually report for the remaining drugs
- Cumulative annually report for all the drugs.

Criteria for a periodic biannually detection/validation report are:

- Product under special surveillance (see List of medicinal products under additional monitoring);
- Product for which a signal has been detected and is being evaluated by the ANSM, the PRAC or the MA (Marketing Authorization) holder (refer to the table of signals and risks monitored by UM
- Product for which a national investigation is underway;
- Product for which a further assessment UNC (Non-Conforming Use) Report has been transmitted to a National Competent Authority;
- Product for which more than 20 cases over the previous year have been collected.

If a signal is validated, a further assessment is needed. This report includes analysis of data from:

- Cumulative data from the Laboratoires CRINEX's safety database
- Clinical trial data;
- A search of the scientific literature;
- Epidemiological data;
- Experimental and/or pre-clinical data;
- Databases such as EudraVigilance or EVDAS;
- Information from International Competent Authorities, in particular the FDA (U.S. Food and Drug Administration), CADTH (Canadian Agency for Drugs and Technologies in Health), Health Canada and MHRA (Medicines and Healthcare products Regulatory Agency), or published by the WHO (World Health Organization) and the UPPSALA Monitoring Centre ;
- Data from the latest PSUR and PSUR single assessment (PSUSA);
- Information from other originator drug containing the same active substance (or belonging to the same pharmacological class) and marketed in France.

If the validated signal is an emerging safety issue, the EU QPPV informs competent authorities within 3 working days by notifying in writing as an Emergency Safety Issue to the competent authorities in Member States where the medicinal product is authorized and to the Agency via e-mail at the address P-PV-emerging-safety-issue@ema.europa.eu

- **Periodic report**

Cases analysed: valid and invalid cases, medically confirmed and non-confirmed, with a received date during the period. Reactions analysed: serious, non-serious, expected, unexpected.
Qualitative method is performed for cases below:

- Fatal cases;
- Cases with a PT included in the DME (Designated Medical Event) list;
- Serious cases (not included in the DME list) with expected or unexpected PT when there are three (3) or more cases during the period analyzed;
- Non-serious cases with expected or unexpected PT when the number of non-serious cases for the drug has increased by more than 50% from the previous period and there are three (3) or more cases during the analysis period;
- Serious and non-severe cases reporting a particular situation when there are three (3) or more cases during the period analyzed.

In these situations, a summary of cases is presented based on a review of causality, dechallenge, rechallenge, medical history (risk factors), type of population (elderly or paediatric), other associated PT, outcome of the event, other suspected drugs, report type (literature, agency report, spontaneous), medication errors, known reasons explaining the increase of the number of cases reported. Conclusion for signal detected or not is based on this evaluation.

- **Annually report**

Cases analysed: valid and invalid cases, medically confirmed and non-confirmed. Reactions analysed: serious, non-serious, expected, unexpected.
For each drug, number of cases per year is presented. Explanations for increase / decrease in the number of cases are provided.
Quantitative method (statistical analysis) based on the PRR (Proportional Reporting Ratio) is performed using cumulative data for each drug. Statistical significant associations are presented in the report when the lower value of the confidence interval Proportional Reporting Ratio (PRR) is greater than 1, and the number of found cases is greater than 3. A summary of cases is performed if the maximum number of reported cases for Preferred Terms (PTs) occurred in the last year. Cases during the last year are summarized. However, if there are cumulatively less than 10 cases with the PT, all cases in the database with the PT are summarized.
5.4 Responses to the Authorities
If Laboratoires CRINEX or UNIVERSAL MEDICA receives a request from any health authority related to pharmacovigilance, benefit/risk ratio of a product (pharmacovigilance survey, particular monitoring of a product or therapeutic class, inspection, urgent safety restriction, DHPC, etc.), an e-mail will be sent to the other party on the same day or within not more than 1 business day. If not decided by the requestor, a deadline for answering the questions is defined by Laboratoires CRINEX and UNIVERSAL MEDICA. The procedure PR-VIG-UM-010 “Communication with the Competent Authorities” will be applied by UNIVERSAL MEDICA and the test for Laboratoires CRINEX.
5.5 Risk management system and monitoring of the outcome of risk minimisation measures
The preparation of Risk Management Plan (RMP) is under the responsibility of the EU QPPV who validates and signs RMPs. RMPs are approved and submitted to Competent Authorities by Laboratoires CRINEX.
A RMP will be created and submitted as per GVP Module V:
For all new marketing applications, the applicant submits the risk management plan describing the risk management system.
In the post-authorisation phase, a RMP update or a new RMP is submitted when:

- A request from the Agency or a competent authority in a Member State states there is a concern about a risk affecting the risk-benefit balance,
- An application involves a change to an existing marketing authorisation with data leading to a change in the list of the safety concerns, or new additional pharmacovigilance activity or a new risk minimisation

activity needed or proposed to be removed. The RMP update can be warranted as a result of data submitted with applications such as new or significant change to the indication, a new dosage form, a new route of administration, a new manufacturing process of a biotechnologically-derived product.

The need for a RMP or an update to the RMP is discussed with the Agency or a competent authority in a Member State, as appropriate, well in advance of the submission of an application involving a significant change to an existing marketing authorisation.
The procedure PR-VIG-UM-018 “Gestion des Risques” (Management of Risks) and Laboratoires CRINEX's SOP test will be applied by UNIVERSAL MEDICA
5.6 PSUR/PBRER scheduling, production and submission
PSUR scheduling and writing are taken in charge by UNIVERSAL MEDICA on behalf of Laboratoires CRINEX and are submitted to Competent Authorities by Laboratoires CRINEX. Partners, distributors are in charge of PSUR scheduling, writing and submission to their National Competent Authorities if applicable.
A schedule of PSURs is maintained up to date by UNIVERSAL MEDICA using the EURD list. The update is performed at least annually. The schedule of PSURs for the on-going year is presented during the "Safety Committee".
The PSURs/PBRERs produced by UNIVERSAL MEDICA are written and submitted according to UNIVERSAL MEDICA procedure PR-VIG-UM-004 "DSUR PSUR PBRER ACO writing" and Laboratoires CRINEX's SOP test and work instructions WI-VIG-UM-006 "PSUR PBRER ACO writing" and WI-VIG-UM-008 "Soumission électronique des PSUR".
PSURs are prepared using the format and contents described in the Module VII of the Guideline on good pharmacovigilance practices.
TEXT_PSUR_SIGNED_EUQPPV
5.7 Communication of safety concerns to consumers, healthcare professionals and the competent authorities)
Communication of safety concerns will be done according to the recommendation provided in Good Pharmacovigilance Practices, Module XV – Safety communication. This Module provides guidance to marketing authorisation holders, competent authorities in Member States and the European Medicines Agency on how to communicate and coordinate safety information in the EU.
The process is described within UM's SOP PR-VIG-UM-010 « Communication with the Competent Authorities » and Laboratoires CRINEX's SOP test.
All activities related to Direct Healthcare Professional Communications (DHPC) or patient communications are coordinated by the EU QPPV and the Responsible Pharmacist. Standard phrases may be tested and subsequently used, as appropriate, particularly in urgent situations.
The DHPC is drafted according to the template provided GVP Module XV – Safety Communication. Recipients (Target population) are defined from one or more of the following: general practitioners, specialists, pharmacists, hospital pharmacists, wholesalers, lay public, media. The translated DHPC, timetable for release and recipients are submitted to the Competent Authorities for approval. Recipient’s addresses are retrieved from the appropriate databases by Laboratoires CRINEX. Depending on the volume, distribution is performed by Laboratoires CRINEX or a media agency.
Once the content of the DHPC and patient communication plan have been approved by the relevant Competent Authorities, the DHPC and patient communication will be disseminated (in line with the communication plan provided in Good Pharmacovigilance Practices, Module XV – Safety communication for DHPC).
5.8 Implementation of safety variations to the summary of products characteristics and patient information leaflets
Triggers for updates to the SmPC and patient information leaflets which may arise through a number of routes including ongoing safety monitoring, analysis of data in the PSUR or from any signal are reviewed and approved by the QPPV and Responsible Pharmacist.
The timelines to file variations aiming to change the SmPC are those imposed by the National Competent Authorities addressing a formal request to Laboratoires CRINEX or the timelines stated in the Laboratoires CRINEX's SOP test.
The timelines to file variations are in the tracker used for Regulatory Affairs. Timelines are:.....The EU QPPV is aware of the new product information within 15 working days after their approval by the Competent Authorities.
Implementation of leaflets: The Responsible Pharmacist is responsible for implementing the patient leaflets in relation with the manufacturing site.

6. Pharmacovigilance system performance

6.1 ICSR reporting

6.1.1 Assessment of Correct ICSR Reporting

The purpose of ICSR submission compliance monitoring is to identify occurrences of non-compliant ICSR submissions to competent authorities, as well as to identify root causes for non-compliances. Appropriate corrective and preventive actions are to be implemented, promoting adherence to regulatory requirements.
Reportable ICSRs are submitted electronically or, in cases where this is not possible, via other means (e.g. e-mail, fax… to competent authority).
The performance of ICSR processing is guaranteed within UNIVERSAL MEDICA by applying its own currently valid SOPs referenced as PR-VIG-UM-001 (Pharmacovigilance Cases Management). Respect of timelines for submission is a performance indicator presented in annex F.
In case of submission delay, the EU QPPV is immediately informed and appropriate corrective and preventive actions are taken.
The procedure test is used by Laboratoires CRINEX to check the timelines between the data-entry and the ICSR submission.
Reconciliation on reporting are handled on regular test basis between Laboratoires CRINEX and UNIVERSAL MEDICA in order to check if no ICSR has been missed.

6.1.2 Monitoring ICSR Submission Quality

The acknowledgment of receipt received from EudraVigilance, provides immediate feedback on the correctness and completeness of the information submitted.
The PV Officer tracks from EudraVigilance the Acknowledgement Messages (ACK) of the submission (XML format). They are electronically saved. In case of incorrect submission, appropriate corrective actions are immediately taken and the ICSR concerned is reviewed to be correctly submitted.

6.2 PSUR reporting

The SOP test is used by Laboratoires CRINEX to check the correct timeline of PSUR reporting. This quality indicator is the on-time submission of the PSUR to the competent authority.

6.3 Safety Variation Submissions

The SOP test is used by to check the correct timeline of safety variation submission. The quality indicator is the on-time submission of the safety variation to the competent authority.

6.4 RMP commitments

The EU QPPV is responsible for the implementation and the follow-up of the risk management plan commitments or other obligations or conditions of marketing authorizations.
A table showing the adherence to risk management plan and other obligations or conditions of marketing authorisations is inserted in Annex F3.

7. Quality system

Quality management systems applicable to pharmacovigilance activities are settled at Laboratoires CRINEX, and at UNIVERSAL MEDICA, each system being applicable to the pharmacovigilance activities performed at each site.

7.1 Document management and record control

PSMF

An electronic copy of the PSMF is saved on the server of UNIVERSAL MEDICA with limited access to EU QPPV, deputy EU QPPV and UNIVERSAL MEDICA's collaborators dedicated to Laboratoires CRINEX Each time the PSMF version is upgraded, the previous version is archived electronically by the IT department, according to the methods described in procedure PR-QA-UMG-003 (Archiving). Archived versions are kept for a minimum of 5 years.

Other documents

Other documents related to pharmacovigilance activities are stored and archived according to the following processes:

- For documents produced at Laboratoires CRINEX: Décrire le système de conservation et d'archivage des données du client.
- For documents produced at UNIVERSAL MEDICA: Original paper documents are scanned and keep in a fireproof waterproof key closed cabinet. Electronic documents are stored on UNIVERSAL MEDICA's server and are available to all collaborators dedicated to Laboratoires CRINEX via the company's intranet. At the end of the contract, any file created and handled on behalf of Laboratoires CRINEX is returned to Laboratoires CRINEX which keeps the final responsibility of archiving, as specified in the contract between Laboratoires CRINEX and UNIVERSAL MEDICA.

7.2 Procedural documents

Quality system applicable to pharmacovigilance activities settled at Laboratoires CRINEX and UNIVERSAL MEDICA, are composed as follows:

Laboratoires CRINEX

These documents are under the responsibility of the quality Assurance department of Laboratoires CRINEX who plans their periodic revision, ensures their diffusion, restricts their access and archives them.

Collaborators have to be aware and be trained to the SOPs and Work Instructions relevant to their activities. This is tracked by signing the form associated with the procedures. The procedure is applicable starting from the date of application. Update is scheduled at least every 3 years.

UNIVERSAL MEDICA:

UNIVERSAL MEDICA Quality Management System documentation contains:

- The quality manual describing the general organization of UNIVERSAL MEDICA GROUP on Quality policy. It is approved by the Direction, who ensures that the provisions described are consistent with the "quality" objectives of UNIVERSAL MEDICA.
- Standard Operating Procedures describing the operations to be performed in a domain for executing one or more tasks.
- The working instructions that are detailed descriptions specific to the execution of a given operation or task.
- The organizational charts.
- The specifications, functional specifications, technical specifications, validation plans, risk analyses, validation reports that are dedicated to IT developments.

Collaborators have to be aware and be trained to the SOPs and Work Instructions relevant to their activities. This is tracked by acknowledging receipt of the document in the electronic document management system Qualios. The procedure is applicable starting from the date of application. Update is scheduled at least every 3 years.

A list of the quality documents applicable to pharmacovigilance activities for the products referenced in Annex H is attached in Annex E.

7.3 Training

Organization charts in Section 2 of the PSMF provide accurate information regarding collaborators involved in

the routine pharmacovigilance activities of the products concerned by this PSMF.

Laboratoires CRINEX

All Laboratoires CRINEX collaborators are recruited based on adequate qualifications and experience. As Laboratoires CRINEX performs pharmaceutical activities, each incoming and existing collaborator (even those that do not perform pharmaceutical tasks) receives an initial pharmacovigilance and good manufacturing practices training and once yearly thereafter. The training and corresponding evaluation are in the form of an e-learning managed by an external partner having the necessary professional background and experience.
If the results of the multiple-choice online evaluation are not satisfactory after 2 trials (passing 80%), necessary measures are agreed upon a timely fashion. The collaborator will have a face to face PV training. The collaborator will then perform again the online training and will have to pass again the online evaluation.

A statement of training, mentioning the evaluation results is provided to Laboratoires CRINEX by the partner. Besides the documentation of internal and external training documents, each collaborator's record file consists of the individual's job Description as well as further documentation of CV and Diploma. The record file is archived within Laboratoires CRINEX's premises at Saint-Cloud.
The manager determines which training each collaborator should receive according to their assigned tasks.

UNIVERSAL MEDICA

Each UNIVERSAL MEDICA collaborator is recruited on the basis of its adequate qualifications and experience. As UNIVERSAL MEDICA performs pharmacovigilance activities, each incoming and existing UNIVERSAL MEDICA personnel (even those that do not perform pharmacovigilance tasks) receives an initial pharmacovigilance training and refresh annually. The training is in the form of an e-learning prepared by the PV department and an evaluation is required. If the UNIVERSAL MEDICA staff fails to pass the multiple-choice online evaluation after 3 trials (passing score is 80%) necessary measures are agreed upon a timely fashion. The collaborator will have a face to face PV training. The collaborator will need to pass the online evaluation.

The evaluation results are stored in the e-learning platform or electronically by QA service. Besides the documentation of internal and external training documents, each collaborator's record file consists of the individual's Job Description as well as further documentation of CV and Diploma. The record files are handled by the QA service. The pharmacovigilance project manager determines which training each collaborator must receive according to its assigned tasks by following a training matrix. After the training, the collaborator must sign the FO-QA-UMG-007 « Feuille de présence - Attendance Sheet ». Moreover, and if available, the collaborator will be aware and trained to the specific client's work instruction.7.4 Auditing and CAPAs

Pharmacovigilance systems settled to allow the management of routine PV activities for products listed in **Annex H** are regularly audited by the different entities acting together in this Pharmacovigilance system.

List of audits conducted and completed for the past 5 years and audits scheduled for the next 5 years are attached in **Annex G**, along with the status of CAPA plans when applicable.

In addition, significant findings raised during audits and inspections, unresolved at the time the version of this PSMF, fulfilling the EU criteria for major or critical findings according to GVP module IV are indicated below.7.4.1 Audit at Laboratoires CRINEX

The audit process is described in the current version of the procedure test.
Décrire le système d'audit du client7.4.2 Audit of UNIVERSAL MEDICA by Laboratoires CRINEX

Laboratoires CRINEX or a service provider on behalf of Laboratoires CRINEX performs audits, following the process describes in the current version of procedure test.
Following items are under the scope of audit:

- Legal and administrative aspects (documentation of the responsible parties for pharmacovigilance or drug safety activities, availability of information on all suspected adverse events at least at a single point, contractual documentation with respect to any pharmacovigilance/drug safety responsibilities being out-sourced, documentation regarding the delegation of responsibilities for pharmacovigilance/drug safety

with respect to co-marketing agreements, preparation and submission of PSUR/SmPCs, collection and reporting of spontaneous adverse events, collection, follow up and reporting of pregnancy exposure, collection, follow up and reporting of paediatric population exposure...)
- Organisational structure (quality system and standard operating procedure for pharmacovigilance activities, qualified person, resources and training of personnel...)
- Facilities and computer systems (computer system in use, migration of data and legacy system, system for archiving and retrieval of documents, archiving and filing facilities, controlled access to the archives...)
- Safety information from other departments (quality defects, medical information, legal information...)
- Data/documentation review

Based on the observations made, an audit report is prepared, addressing the findings (critical, major or minor), providing an evaluation of their impact, and a recommendation for the actions to be taken. Audit report is compiled by Laboratoires CRINEX. Audit is closed when the CAPA plan is realised.7.4.3 Audits by UNIVERSAL MEDICA including internal audits

A risk-based approach is handled by UNIVERSAL MEDICA in relation with the Pharmacovigilance system in order to determine the areas, processes or activities subject to higher risks (WI-VIG-UM-013 “Méthode d'analyse de risque pour la planification d'audits internes en pharmacovigilance »).

The overall performance of the pharmacovigilance system is audited by self-inspections initiated by the UNIVERSAL MEDICA staff in cooperation with the QA representative of UNIVERSAL MEDICA at least three years. It is the responsibility of the QA Representative to decide the frequency and scope of audits. The QA representative is also responsible for reviewing the corresponding report and for initiating appropriate measures in case of insufficient performance or quality.

In line with all other SOPs, those that relate to QA topics are updated on an on-going basis by UNIVERSAL MEDICA’s QA Representative appointed by the General Management.

Every year the QA Representative defines an internal audit plan providing a schedule covering all quality relevant systems and processes at UNIVERSAL MEDICA over the next 12 months.

The UNIVERSAL MEDICA procedure PR-QA-UMG-010 “Audits” provides information on the planning, execution (preparation, conduct, and audit report) and monitoring of the results of the audit reports.7.4.4 Note in relation with audit findings

This section records and elaborates on the significant findings

- raised during audits and inspections
- under resolution at the time the version of this PSMF main body is issued
- meeting the criteria for major and critical according to section 2.2.2 of GVP module IV.

Laboratoires CRINEX

Reference and date the finding has been raised	Wording of the significant finding	Criticity of the finding	CAPA	Expected resolution date	Effective resolution date
None					

Laboratoires CRINEX

Reference and date the finding has been raised	Wording of the significant finding	Criticity of the finding	CAPA	Expected resolution date	Effective resolution date
None					

Safety database eVeReport® (eVeDrug)

Reference and date the finding has been raised	Wording of the significant finding	Criticity of the finding	CAPA	Expected resolution date	Effective resolution date
None	Some aspects of personal data protection are not appropriately covered: • contractual agreements between eVeDrug and Universal Medica, and between eVeDrug and Claranet do not include required GDPR clauses (Art. 28) the eVeReport analysis is not finalized in terms of privacy impact assessment and description of existing technical and organizational measures (to assist the controller in ensuring compliance with its GDPR/CNIL obligations related to data protection) GDPR, CNIL RS-001	MAJOR	Finalizing eVeReport privacy impact assessment: • eVeDrug/UM contact: amendment including GDPR clauses signed on Dec 12th, 2019 Claranet is HDS certified (Hébergeur de Données de Santé) therefore RGPD compliant	31DEC2020	

LONGTEXT_FINDINGS_UM7.4.5 Deviations from pharmacovigilance procedures

In case of non-compliance to pharmacovigilance procedures, underlying reasons have to be analysed (root cause analysis), documented and appropriate corrective and preventive actions (CAPA) have to be defined and implemented. At UNIVERSAL MEDICA the process for deviations management is described in the SOP PR-QA-UMG-009 “Maîtrise des non-conformités, des réclamations et des actions correctives et préventives ».

List of unresolved deviations:

Laboratoires CRINEX

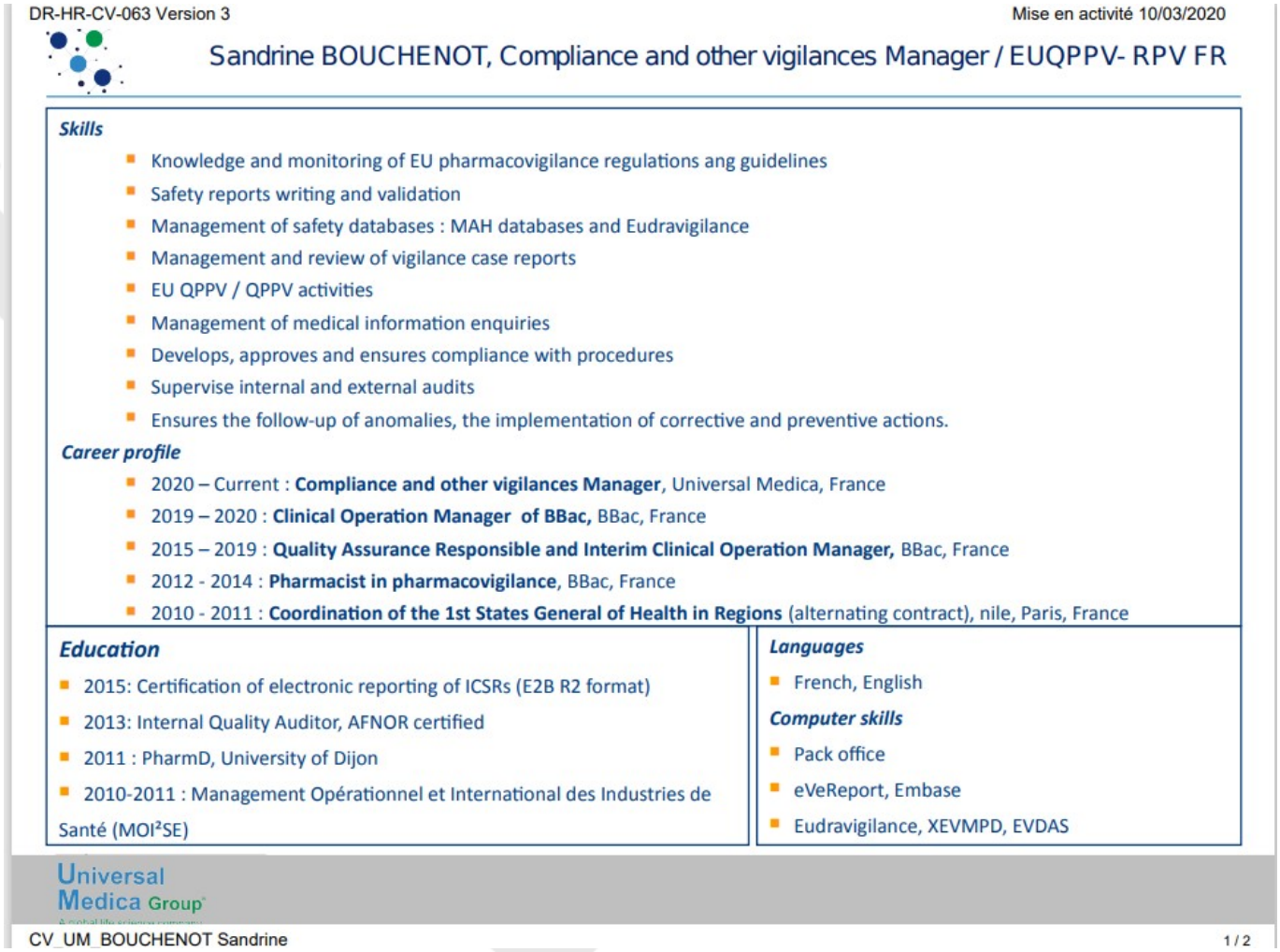
Deviation reference	Date	Procedure concerned	Status
None			

UNIVERSAL MEDICA

Deviation reference	Date	Procedure concerned	Status

ANNEX A: Qualified Person Responsible for Pharmacovigilance
ANNEX B: MAH Organisational Structure
ANNEX C: Safety Data Sources
ANNEX D: Computerized Systems and Safety Databases
ANNEX E: Pharmacovigilance Process and Written Procedures
ANNEX F: Pharmacovigilance System Performance
ANNEX G: Quality System
ANNEX H: Products
ANNEX I: Document and Record Control

Annex A : EU QPPVAnnex A1.: EUQPPV curriculum vitae



DR-HR-CV-063 Version 3

Mise en activité 10/03/2020

Sandrine BOUCHENOT, Compliance and other vigilances Manager / EUQPPV- RPV FR

Skills

- Knowledge and monitoring of EU pharmacovigilance regulations ang guidelines
- Safety reports writing and validation
- Management of safety databases : MAH databases and Eudravigilance
- Management and review of vigilance case reports
- EU QPPV / QPPV activities
- Management of medical information enquiries
- Develops, approves and ensures compliance with procedures
- Supervise internal and external audits
- Ensures the follow-up of anomalies, the implementation of corrective and preventive actions.

Career profile

- 2020 – Current : **Compliance and other vigilances Manager**, Universal Medica, France
- 2019 – 2020 : **Clinical Operation Manager of BBac,** BBac, France
- 2015 – 2019 : **Quality Assurance Responsible and Interim Clinical Operation Manager,** BBac, France
- 2012 - 2014 : **Pharmacist in pharmacovigilance**, BBac, France
- 2010 - 2011 : **Coordination of the 1st States General of Health in Regions** (alternating contract), nile, Paris, France

Education

- 2015: Certification of electronic reporting of ICSRs (E2B R2 format)
- 2013: Internal Quality Auditor, AFNOR certified
- 2011 : PharmD, University of Dijon
- 2010-2011 : Management Opérationnel et International des Industries de Santé (MOI²SE)

Languages

- French, English

Computer skills

- Pack office
- eVeReport, Embase
- Eudravigilance, XEVMPD, EVDAS

Universal Medica Group

CV_UM_BOUCHENOT Sandrine

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Annex A2: List of tasks that have been delegated by the EU QPPV

Class	Pharmacovigilance tasks (post marketing)	Location	
		Laboratoires CRINEX	UM
QPPV	EU and local QPPV	X	
	Deputy EU-QPPV	X	
	PSMF writing and updates	X	
	SDEA writing	X	
	SDEA review and approval	X	
On call duty	Pharmacovigilance and medical information	X	
	Other calls	X	
ICSR	Collection of cases	X	
	Evaluation of cases	X	
	Safety database case entry	X	
	Case referencing, communication and investigation with reporter	X	
	Approbation, coding and classification, imputability	X	
	Submission, reporting through/in Eudravigilance	X	
	Medical assessment	X	
	EudraVigilance L2A Request	X	

	Periodic reconciliation	X	
SIGNAL DETECTION AND ANALYSIS	Periodic signal detection/validation	X	
	Cumulative signal detection/validation	X	
	Quarterly Overall evaluation (safety committee)	X	
	Prioritisation of signal detected	X	
	Further assessment of signal, recommendations for actions	X	
	Notification of emerging safety issues	X	
RISK MANAGEMENT PLAN	RMP writing and approval	X	
	Approval and Filing to Authorities	X	
LITERATURE	MLM literature monitoring	X	
	Local non indexed literature monitoring	X	
	International literature monitoring (Embase, Medline)	X	
PSUR	Monitoring of schedule	X	
	Sales data, official documentation, MA, SmPC, leaflet	X	
	PSUR writing	X	
	Quality control on PSUR	X	
	Approval and Submission to Authorities	X	
STUDY MANAGEMENT	Pre-authorization	X	
	Post-authorization	X	
SAFETY DATABASE	Data base administration, validation	X	
REGULATION	Weekly regulatory watch	X	
XEVMPD	Populate Product and SmPC updates	X	
QUALITY SYSTEM	Handle documentation, SOP, audit, inspection and CAPA	X	
	Provide Key Performance Indicators	X	
	Approve Key Performance Indicators	X	
TRAINING	Training of company personal as appropriate	X	
	Training of Sales representatives	X	
INFORMATION	Provide reference medical and pharmaceutical information on products	X	
	Response to inquiries according to reference information	X	
	Response to inquiries other than included in reference information	X	
MA	Handle Safety variation of Marketing Authorization	X	
PACKAGING COMPONENTS	Update packaging components i.e. patient leaflet	X	
COMMUNICATION	Handle communication to Health Professionals and Patients	X	

Annex A3: Contact details of the EU QPPV

EU QPPV

BOUCHENOT Sandrine
Universal Medica
13 rue Henri Matisse, 77 000 La Rochette
Tel: (01) 64 79 54 13
Mobil: (06) 08 28 52 11
Fax: (01) 64 79 54 13
e-mail: sandrine.bouchenot@universalmedica.com

Annex A4: Summary of Eudravigilance registration

Annex A5. : Information on pharmacovigilance contact person nominated at national level

France

Laboratoires CRINEX has nominated test test, Person responsible for Pharmacovigilance in France. The French Health Authority was informed of this nomination by post on 2021-01-01.

Contact details are :

Name	test test
Function	FR_RPV_FUNCTION
Address	test
Telephone	test
Fax	test
e-mail	test

Missions are :

- collect, process and make available the information on suspected adverse reactions due to medicinal products operated by Laboratoires CRINEX to any authorised person and the people who make information through canvassing or prospecting for medicinal products;
- set up and manage the pharmacovigilance system and risk management system;
    - all suspected serious adverse reactions, which occurred in a Member State of the European Union or a State party to the agreement on the European Economic Area or a third country, which he has knowledge, without delay and at the latest within fifteen days of receipt of the information;
    - all suspected non-serious adverse reactions, which occurred in a Member State of the European Union or a State party to the Agreement on the European Economic Area, which it has knowledge, within the ninety days following the receiving information;
    - periodic safety update report (PSUR);
- ensure the implementation and monitoring of the measures described in the European risk management plan at national level as well as specific measures on the national territory requested by the ANSM, such as enhanced surveillance or risk reduction activities, and also monitor the results of risk reduction measures;

- ensure the implementation of procedures to obtain accurate and verifiable data for the realisation of the scientific evaluation of suspected adverse reaction reports, collect additional information on these reports and send the updates to the Eudravigilance database;
- ensure that it is answered fully and promptly to the demands of the ANSM, Pharmacovigilance Regional Center and Center for Evaluation and Information on Drug Dependence (CEIP-A);
- implement the necessary measures for the detection and validation of signals and cooperate in the evaluation of a confirmed signal in accordance with the modalities described in Module IX of the GVP including the estimation of the incidence of suspected adverse reactions (or otherwise the rate of notifications);
- to have the elements guaranteeing SYS_test the control of the computerized systems used in the framework of the execution of the activities of pharmacovigilance, their validation and their maintenance in the validated state;
- provide to the ANSM any other information relevant to the evaluation of benefice-risks related to a medicinal product, including both positive and negative results of biomedical research and studies of safety and effectiveness for all indications and populations, whether or not mentioned in the marketing authorisation, as well as data regarding any improper use of medication under the Marketing Authorisation and all information relating to sales volume and prescription for the medicinal product concerned.

According to the French Health Authorities, the Accountable pharmacist of Laboratoires CRINEX is responsible for all the PV activities from a legal point of view. Nevertheless. He has delegated the responsibility local Qualified Person for Pharmacovigilance for the products listed in Annex H.

IMG_ANSM_LETTRE

Note Universal Medica : ajouter les différents pays EEA du client et préciser si besoin ou non. Si besoin d'un contact local, préciser, qui, coordonnées, missions/responsabilités si existant copie courrier de nomination. Pour les pays ci-dessous, confirmer ou se faire confirmer par un partenaire du client les requis nationaux.
La liste des exigences locale est disponible sur le site de l'EMA :
https://www.ema.europa.eu/en/documents/other/information-member-states-requirement-nomination-pharmacovigilance-phv-contact-person-national-level_en.pdf

Appendix B : MAH organisational structureAppendix B.1 : List of contracts and agreements

Activity	Concerned parties	Nature ofthecontract	Date ofAgreement	Concernedproducts	Concernedterritories	Contact point (name, address, telephone and e-mail)	PV activities /services subcontracted
Service providers	Universal Medica	Third party for medical information and Pharmacovigilance activities ofLaboratoires CRINEX	<DD-MMM-YYYY>	All products			
Other Technical providers	Telephone and internet (third party for Universal Medica)		May-2004	All products			
OVH	Telephony failover and Medicasource host	Servers: May-2008 Internet: Mar-2015 Telephony: Apr-2016		All products			
Ovid Insights Ed. Wolker Luwers	Bibliographic researchtool including Embase and MedlineInternational biomedical bibliographic data bases.	##	All products				
eVeDrug	Safety Database eVeReport® (third party for Universal Medica)	##	All products				
Commercialarrangements							

Annex C: Safety data sources

Sources of safety data are listed in the appendix B (commercials arrangements) and in the chapter “Safety data sources”

Annex D: Computerised systems and Safety Databases

Safety databases and computerized systems:

Name	Function
eVeReport	Safety database for case management
MedicaSource	Management of medical information

Organization of computer systems of Laboratoires CRINEX.

Name	Function
	Work in direct
	Local and remote daily backup

Organization of computer systems of Universal Medica.

Annex E: Pharmacovigilance processes and written proceduresAnnex E1: Lists of Laboratoires CRINEX procedural documents

Reference code	Version	TITLE	Applicable Date

Annex E2: Lists of UNIVERSAL MEDICA procedural documents

SOP code	Document type	Title	Effective Date
General activities			
WI-VIG	Work instructions	Client's WI	DD/MM/YYYY
DR-VIG-UM-005	Reference Document	Référentiel des textes législatifs et réglementaires (Regulatory references)	14/10/2020
DR-VIG-UM-006	Reference Document	Liste des définitions dans le domaine des vigilances (Definitions list in Vigilances Context)	14/10/2020
DR-VIG-UM-008	Reference Document	Structure des équipes PV et suppléance des fonctions (pharmacovigilance team organisation and substitution of functions)	19/06/2020
DR-VIG-UM-009	Reference Document	Liste des actions pouvant être menées en cas d'évolution de la liste de produit client (List of actions that can be implemented when the client's product list is updated)	24/09/2020
DR-VIG-UM-011	Reference Document	Plan de continuité des activités de pharmacovigilance (Pharmacovigilance business continuity plan)	11/12/2020
PR-EXM-UMG-001	SOP	Mise en oeuvre du Plan de Continuité d'Activité (Universal Medica Business Continuity Plan)	21/08/2020
PR-EXM-UMG-002	SOP	Achat et gestion des fournisseurs (Purchase and management of suppliers)	17/08/2020
QPPV activities			
PR-VIG-UM-003	SOP	Procédure sur la fonction QPPV (Procedure on the function of QPPV)	09/11/2020
PR-VIG-UM-007	SOP	Gestion du dossier permanent du système de pharmacovigilance (Redaction of a pharmacovigilancesystem master file)	19/06/2020
WI-VIG-UM-010	Work instructions	Safety Committee	22/06/2020
Partner activities			
DR-VIG-UM-002	Reference Document	SDEA Template	24/06/2020
DR-VIG-UM-003	Reference Document	Clause de Pharmacovigilance – template (Clause of Pharmacovigilance - template)	22/07/2020
PR-VIG-UM-012	SOP	Gestion des partenaires de distribution et promotion (Management of promotional and distribution partners)	09/12/2020
DR-VIG-UM-010	Reference Document	Analyse de risque pourla planification des audits des partenaires ayant une activité PV ou d'information médicale (Risk analysis for the audits planning of partners with a PV or medical information activity)	23/11/2020
ICSR management			
PR-VIG-UM-016	SOP	Gestion d'un usage non conforme (Management of a non-appropriate use)	24/06/2020
PR-VIG-UM-002	SOP	Imputabilité en pharmacovigilance (Imputability in Pharmacovigilance)	10/03/2020
PR-VIG-UM-001	SOP	Pharmacovigilance cases management	11/06/2020

SOP code	Document type	Title	Effective Date
WI-VIG-UM-011	Work instructions	Modalités pratiques de gestion d'un cas de pharmacovigilance (Pratical management of a pharmacovigilance case)	31/10/2020
PR-VIG-UM-005	SOP	Veille bibliographique en pharmacovigilance (Pharmacovigilance Literature monitoring)	08/06/2020
WI-VIG-UMG-001	Work instructions	Suivi des abonnements et de la réception des revues papiers non indexées pour la veille bibliographique (Monitoring of subscriptions and the reception of unindexed paper journals for the literature review)	27/12/2018
WI-VIG-UM-002	Work instructions	Modalités pratiques de veille en pharmacovigilance dans les revues papiers et les bases de données (Practical methods of monitoring in pharmacovigilance in paper journals and databases)	05/01/2021
WI-VIG-UM-016	Work instructions	Stratégie de veille de la littérature locale et internationale (Strategy for monitoring local and international literature)	21/09/2020
PR-VIG-UM-006	SOP	EudraVigilance management on behalf of a client	25/11/2020
WI-VIG-UM-004	Work instructions	Management of EudraVigilance Monitoring	17/07/2020
WI-VIG-UM-007	Work instructions	Electronic transmission of ICSRs to EudraVigilance	22/06/2020
PR-VIG-UM-017	SOP	Gestion des bases de données en Pharmacovigilance (Safety database management)	22/09/2020
Risk/benefit monitoring			
PR-VIG-UM-008	SOP	Gestion du signal en pharmacovigilance (Signal Management in pharmacovigilance)	23/11/2020
WI-VIG-UM-015	Work instructions	Modalités pratiques pour la détection du signal (Practical arrangements for signal detection)	20/11/2020
PR-VIG-UM-018	SOP	Gestion des risques (Risk Management)	27/02/2020
PSUR/PBRER management			
PR-VIG-UM-004	SOP	DSUR PSUR PBRER ACO RMP Writing	06/07/2020
WI-VIG-UM-006	Work instructions	PSUR PBRER ACO writing	17/09/2020
WI-VIG-UM-008	Work instructions	Soumission électronique des PSURs (Electronic transmission of PSURs)	15/04/2020
Communication of safety concerns			
PR-VIG-UM-010	SOP	Communication with the Competent Authorities	09/12/2020
Medical Information management			
PR-MI-UMG-001	SOP	Medical Information enquiry handling	30/10/2020
Quality system			
DR-VIG-UM-001	Reference Document	Matrice de formation en Pharmacovigilance (Training schedule in Pharmacovigilance)	15/12/2020
FO-QA-UMG-007	Form	Feuille de présence - Attendance Sheet	27/12/2018
PR-QA-UMG-001	SOP	Gestion de la documentation qualité (Quality document management)	05/01/2021
PR-QA-UMG-002	SOP	Revue de la direction de la démarche Qualité (Management review of the Quality approach)	21/05/2020
PR-QA-UMG-003	SOP	Archivage (Archiving)	14/08/2020

SOP code	Document type	Title	Effective Date
PR-QA-UMG-005	SOP	Respect des obligations en matière de protection des données personnelles (Compliance with personal data protection obligations)	14/12/2020
PR-QA-UMG-006	SOP	Veille réglementaire et veille juridique (Regulatory monitoring and legal monitoring)	06/07/2020
PR-QA-UMG-009	SOP	Maîtrise des non-conformités, des réclamations et des actions correctives et préventives (Control of non-compliances, complaints and preventive actions)	05/01/2021
PR-QA-UMG-010	SOP	Audits	18/08/2020
WI-VIG-UM-013	Work instructions	Méthode d'analyse de risque pour la planification d'audits internes en pharmacovigilance (Risk analysis method for planning internal pharmacovigilance audits)	16/04/2020
WI-VIG-UM-014	Work instructions	Sélection et planification d'audits prestataires et partenaire de pharmacovigilance (Selection and planning of supplier audits and pharmacovigilance partner)	31/07/2020
Other			
WI-VIG-UM-003	Work instructions	Electronic submission of information on medicinal products for human use	04/11/2020
WI-VIG-UM-017	Work instructions	Gestion des comptes EudraVigilance (EudraVigilance account management)	18/01/2021

Annex E3 : Lists of test procedural documents

Reference code	Version	Title	Applicable Date
OPE-SOP-01		Backup Management	20/06/2018
QUA-SOP-02		Change Management	05/02/2018
QUA-SOP-03		Incident Management	15/11/2019
eVeR-PV-QM-001		Migration Qualification Protocol	

Annex E4: Lists of NAME OF THE OTHER PV SUBCONTRACTOR procedural documents

LONGTEXT_AUTRES_ANNEXE_E

Annex F: Pharmacovigilance system performanceAnnex F1: List of performance indicators used to measure pharmacovigilance activities performance

Indicators	Target	Frequency
Serious cases submitted to EudraVigilance within 15 days after the receipt date	100%	Quarterly
Non serious cases submitted to EudraVigilance within 90 days after the receipt date	100%	Quarterly
Answer to requests from National Competent Authority or EMA within the timelines	100%	Quarterly
Safety variation submitted within the timelines	100%	Quarterly
PSUR submitted to competent authorities within the timelines	100%	Quarterly

Annex F2: Results of last measures performed

Indicators	2018	2019	2020*
Serious cases submitted to EudraVigilance within 15 days after the receipt date	test	test	test
Non serious cases submitted to EudraVigilance within 90 days after the receipt date	test	test	test
Answer to requests from National Competent Authority or EMA in the timelines	test	test	test
PSUR submitted within the timelines	test	test	test

*Data lock point : 2021-01-01Annex F3: Adherence to risk management plan and other obligations or conditions of marketing authorisations To date, Laboratoires CRINEX do not have a Risk Management Plan and no obligation or condition in their marketing authorisations.

Product name	DCI	RMP version	Date

OR

Pharmacovigilance action	Scheduled date for the establishment	Effective date for the establishment	Comments

Annex G: Quality systemAnnex G1.: List of audits performed in the last 5 years (updated yearly)

Audit Date	Auditedcompany	Company / organization auditor	Audited site	Scope of the audit	Date of the report	Completion status of the audit*	Major or critical findings (Yes/no)**
30JAN2017	eVeDrug	INGESITEC / BBac	Paris	Pharmacovigilance database subcontracted activities	09FEB2017	Closed	
22FEB2017	Grita	eVedrug	Paris / Saint Denis	Archiving of data	MAR2017	Closed	
18SEP2018	BBac	Intertek	La Rochette	Internal audit on PV activities	18SEP2018	Closed	
27JUN2019	BBac (subsidiary of UMG)	Universal Medica (subsidiary of UMG)	La Rochette	Internal audit of the case management	20AUG2019	Closed	
17JAN2020	eVeDrug	SUNNIKAN / UM	Paris	Pharmacovigilance database subcontracted activities	10MAR2020	Closed	Yes
05-2017	Aquaray	UNIVERSAL MEDICA with Copwell	Ivry-sur-Seine	Web hosting, qualification audit	NA	Closed	No
19-Oct-2017	eVeDrug	UNIVERSAL MEDICA with Sunnikan	Paris	Pharmacovigilance application and Database eVeReport	22-Nov-2017	Closed	Yes
27-Nov-2018	Ab Cube	UNIVERSAL MEDICA with Sunnikan	Paris	Management of Safety Easy PVTM computerized system	14-Jan-2019	CAPA in progress	Yes
17-18-Jan-2019	UNIVERSAL MEDICA	Intertek	Saint-Cloud	PV activities, Internal audit	06-Feb-2019	Closed	No
25-Mar-2019	UNIVERSAL MEDICA	UNIVERSAL MEDICA with BBac	Saint-Cloud	QualityAssurance	06-Jun-2019	Closed	No
26-Sep-2019	UNIVERSAL MEDICA	UNIVERSAL MEDICA	Saint-Cloud	Medical Information	24-Oct-2019	Closed	No
23-Oct-2019	UNIVERSAL MEDICA	UNIVERSAL MEDICA	Saint-Cloud	Product Quality Complaint management	29-Nov-2019	Closed	No
25-Sep-2020	Aquaray	Universal Medica Group	NA (questionnaire)	Web hosting	29-Sep-2020	No CAPA	NA
13-Oct-2020	Qualios	UNIVERSAL MEDICA	Remote	Qualios application	26-Nov-2020		No
17-Nov-2020	OVID	Universal Medica	Remote	OVID database monitoring and management (questionnaire + remote audit)	18-Jan-2021 A préciser si votre PSMF est mis à jour après cette date sinon mettre Ongoing	CAPA are to be agreed	No

*Awaiting report; CAPA are to be agreed; CAPA in process; Closed

** Unresolved major or critical findings are described in the PSMF

Annex G2.: List of scheduled audits (Updated yearly)

Company Audited	Auditor Company	Planned audit date	Fields of audits
eVeDrug	UM / audit subcontractor	2021-2022	Subcontracted activities
Universal Medica	UM / audit subcontractor	Q1 2021	All PV activities

Company Audited	Auditor Company	Planned audit date	Fields of audits
Universal Medica	Universal Medica	2021	Archiving
eVeDrug	UM / audit subcontractor	2021-2022	Safety database
Universal Medica	Universal Medica	Q1/Q4 2021	Data privacy

Note: doit contenir les audits internes couvrant activités PV et d'intérêt pour la PV, les audits externes de tous les partenaires.
Exemple de « Fields of audits »
Pharmacovigilance subcontracted activities
Regulatory and pharmacovigilance subcontracted activities
Import / Export and Distribution subcontracted activities including PV
Medical representative subcontracted activities including PV
Export promotion subcontracted activities including PV

Annex H: Products

Brand name	INN	MAH	Country of authorisation (EEA)*Authorisation number Initial date of MA	Type of procedure**	Country of marketing (EEA)*	Countries (outside EEA) of marketing #

* Including Iceland, Liechtenstein, Norway
**: Centrally authorised, nationally authorised products, including those authorised through the mutual recognition or the decentralised procedure.
If applicable, the Rapporteur country or Reference Member State
#: List of countries and if applicable specify the authorization number, registration or visa.

Annex I: Document and record controlAnnex I1: Logbook - Change on Main Body in the last 5 years

Comment	Action	Date	Author
Raison Test	edit	May 28, 2021, 9:10 AM	Baptiste D'Argenlieu
Info med	edit	May 26, 2021, 10:05 AM	Baptiste D'Argenlieu
TEST	edit	May 25, 2021, 2:01 PM	Baptiste D'Argenlieu
Test QO	edit	Apr 29, 2021, 1:30 PM	super admin
Test QO	edit	Apr 29, 2021, 1:29 PM	super admin
test QO	edit	Apr 29, 2021, 1:18 PM	super admin
t	edit	Feb 9, 2021, 11:08 AM	super admin

Section	Comment	Action	Date	Author
PV System master file TEXTE_VAR1_OBLIGATOIRE_NR | Information médicale 2 | Information médicale 3 |	MAJ AP	edit	May 28, 2021, 8:34 AM	audrey mail
PV System master file TEXTE_VAR1_OBLIGATOIRE_NR | Information médicale 2 | Information médicale 3 |	Ajout var 5	edit	May 26, 2021, 2:30 PM	Baptiste D'Argenlieu
PV System master file TEXTE_VAR1_OBLIGATOIRE_NR | Information médicale 2 | Information médicale 3 |	TEST var sur draft	edit	May 26, 2021, 10:00 AM	Baptiste D'Argenlieu
2.2 Sites where Pharmacovigilance functions are undertaken	TEST	edit	May 25, 2021, 1:54 PM	Baptiste D'Argenlieu
2. Organisational structure of the marketing authorisation holder	TEST	edit	May 25, 2021, 1:50 PM	Baptiste D'Argenlieu
Header	TEST	edit	May 25, 2021, 9:17 AM	Baptiste D'Argenlieu
PV System master file TEXTE_VAR1_OBLIGATOIRE_NR | Information médicale 2 | Information médicale 3 |	Test QO	edit	Apr 29, 2021, 1:16 PM	super admin
TEST_PART1-1_TESTQO	Test QO suppression partie	delete	Apr 26, 2021, 2:07 PM	super admin
TEST_PART1_TESTQO	test QO réactivation partie	enable	Apr 26, 2021, 2:03 PM	super admin
TEST_PART1_TESTQO	test désactivation QO	disable	Apr 26, 2021, 1:57 PM	super admin
TES_PART1-1-1_TESTQO	Test QO	add	Apr 26, 2021, 1:46 PM	super admin
TEST_PART1-1_TESTQO	Test QO	add	Apr 26, 2021, 1:44 PM	super admin
TEST_PART1_TESTQO	Ajout subsection	edit	Apr 26, 2021, 1:41 PM	super admin

Section	Comment	Action	Date	Author
TEST_PART1_TESTQO	Test fonction édition du template	edit	Apr 26, 2021, 1:40 PM	super admin
TEST_PART1_TESTQO	Création pour test QO	add	Apr 26, 2021, 1:37 PM	super admin
5.2.1 Collection	use br	edit	Mar 29, 2021, 9:33 AM	super admin
4.3 Paper data management	use br	edit	Mar 29, 2021, 9:14 AM	super admin
5.3 Continuous monitoring of product risk/benefit profiles	up LONGTEXT CONTINUOUS MONITORING REPORT	edit	Mar 26, 2021, 11:06 AM	super admin
8. Annexes	up	edit	Mar 25, 2021, 12:26 PM	super admin
8. Annexes	Import template "8 Annexes "	add	Mar 25, 2021, 11:08 AM	super admin
7.4.5 Deviations from pharmacovigilance procedures	Import template "7.4.5 Deviations from pharmacovigilance procedures"	add	Mar 25, 2021, 10:40 AM	super admin
7.4.4 Note in relation with audit findings	Import template "7.4.4 Note in relation with audit findings "	add	Mar 25, 2021, 10:00 AM	super admin
7.4.3 Audits by UNIVERSAL MEDICA including internal audits	Import template "7.4.3 Audits by UNIVERSAL MEDICA including internal audits"	add	Mar 25, 2021, 9:38 AM	super admin
7.4.2 Audit of UNIVERSAL MEDICA by SYS_CLIENT_NAME	Import "7.4.2 Audit of UNIVERSAL MEDICA by <NAME OF THE CLIENT>" template	add	Mar 25, 2021, 9:35 AM	super admin
7.4.1 Audit at SYS_CLIENT_NAME	Import "7.4.1 Audit at SYS CLIENT NAME" template	add	Mar 25, 2021, 9:21 AM	super admin
7.4 Auditing and CAPAs	Import "7.4 Auditing and CAPAs" template	add	Mar 25, 2021, 9:18 AM	super admin
7.3 Training	Update "7.3 Training"	edit	Mar 25, 2021, 9:03 AM	super admin
7.3 Training	Import "7.3 Training" template	add	Mar 25, 2021, 8:56 AM	super admin
7.2 Procedural documents	Import "7.2 Procedural documents "	add	Mar 25, 2021, 8:50 AM	super admin

Section	Comment	Action	Date	Author
7.1 Document management and record control	create "7.1 Document management and record control "	add	Mar 24, 2021, 7:52 PM	super admin
7. Quality system	update "7. Quality system"	edit	Mar 24, 2021, 7:29 PM	super admin
6.4 RMP commitments	Create "6.4 RMP commitments "	add	Mar 24, 2021, 7:22 PM	super admin
6.3 Safety Variation Submissions	Create "6.3 Safety Variation Submissions "	add	Mar 24, 2021, 5:16 PM	super admin
6.2 PSUR reporting	Create " 6.2 PSUR reporting"	add	Mar 24, 2021, 5:14 PM	super admin
6.1.2 Monitoring ICSR Submission Quality	Create partie 6.1.2	add	Mar 24, 2021, 4:41 PM	super admin
6.1.1 Assessment of Correct ICSR Reporting	Create partie 6.1.1	add	Mar 24, 2021, 4:23 PM	super admin
6.1 ICSR reporting	Create partie 6.1	add	Mar 24, 2021, 4:17 PM	super admin
6. Pharmacovigilance system performance	update partie 6	edit	Mar 24, 2021, 4:16 PM	super admin
5.8 Implementation of safety variations to the summary of products characteristics and patient information leaflets	change parent section	edit	Mar 24, 2021, 4:14 PM	super admin
5.8 Implementation of safety variations to the summary of products characteristics and patient information leaflets	Create partie 5.8	add	Mar 24, 2021, 4:09 PM	super admin
5.7 Communication of safety concerns to consumers, healthcare professionals and the competent authorities	Create partie 5.7	add	Mar 24, 2021, 3:04 PM	super admin
5.6 PSUR/PBRER scheduling, production and submission	not allow subsection, not annexe section	edit	Mar 24, 2021, 2:58 PM	super admin
5.6 PSUR/PBRER scheduling, production and submission	Create partie 5.6	add	Mar 24, 2021, 2:47 PM	super admin
5.5 Risk management system and monitoring of the outcome of risk minimisation measures	Create Partie 5.5	add	Mar 24, 2021, 2:39 PM	super admin
5.4 Responses to the Authorities	Create partie 5.4	add	Mar 24, 2021, 2:17 PM	super admin
5.3 Continuous monitoring of product risk/benefit profiles	up	edit	Mar 24, 2021, 1:53 PM	super admin

Section	Comment	Action	Date	Author
5.3 Continuous monitoring of product risk/benefit profiles	create partie 5.3	add	Mar 24, 2021, 9:38 AM	super admin
5.2.4 Monitoring of the scientific and medical literature	add partie 5.2.4	add	Mar 23, 2021, 1:45 PM	super admin
5.2.3 Submission of reports	add partie 5.2.3	add	Mar 22, 2021, 4:58 PM	super admin
5.2.2 Management	Add partie 5.2.2	add	Mar 22, 2021, 3:55 PM	super admin
5.2.1 Collection	update 5.2.1 Collection	edit	Mar 22, 2021, 3:52 PM	super admin
2.4 Links with other organisations	remove LONGTEXT PROCEDURE CLIENT	edit	Mar 22, 2021, 3:09 PM	super admin
2.2 Sites where Pharmacovigilance functions are undertaken	update partie 2.2	edit	Mar 22, 2021, 2:42 PM	super admin
1.5 Local person for Pharmacovigilance	SYS EUQPPV HIS HER right	edit	Mar 22, 2021, 2:20 PM	super admin
1.5 Local person for Pharmacovigilance	use FR RPV HIS HER	edit	Mar 22, 2021, 2:11 PM	super admin
1.4 Back-up arrangement	update partie 1.4	edit	Mar 22, 2021, 2:07 PM	super admin
PV System master file TEXTE_VAR1_OBLIGATOIRE_NR | Information médicale 2 | Information médicale 3 |	add "Conséquence Choix 1, option 1 ou 2"	edit	Mar 22, 2021, 1:55 PM	super admin
5.2.1 Collection	create 5.2.1 Collection	add	Mar 19, 2021, 5:00 PM	super admin
5.2 ICSR collection, collation, follow-up, assessment and reporting	allow sub section	edit	Mar 19, 2021, 4:54 PM	super admin
4.3 Paper data management	r	edit	Mar 19, 2021, 4:53 PM	super admin
4.2 Computerised data management	r	edit	Mar 19, 2021, 4:53 PM	super admin
4. Computerised systems and databases	r	edit	Mar 19, 2021, 4:53 PM	super admin
3. Safety data sources	r	edit	Mar 19, 2021, 4:53 PM	super admin

Section	Comment	Action	Date	Author
2.4 Links with other organisations	r	edit	Mar 19, 2021, 4:53 PM	super admin
2.2 Sites where Pharmacovigilance functions are undertaken	r	edit	Mar 19, 2021, 4:52 PM	super admin
2. Organisational structure of the marketing authorisation holder	r	edit	Mar 19, 2021, 4:52 PM	super admin
1.5 Local person for Pharmacovigilance	r	edit	Mar 19, 2021, 4:52 PM	super admin
1.4 Back-up arrangement	r	edit	Mar 19, 2021, 4:52 PM	super admin
1.3 Contact details	r	edit	Mar 19, 2021, 4:52 PM	super admin
1.2 QPPV Summary Curriculum vitae	r	edit	Mar 19, 2021, 4:52 PM	super admin
1.1 Description of the responsibilities guaranteeing that the QPPV has sufficient authority over the pharmacovigilance system	r	edit	Mar 19, 2021, 4:51 PM	super admin
1. Qualified person responsible for pharmacovigilance (QPPV)	r	edit	Mar 19, 2021, 4:51 PM	super admin
5. Pharmacovigilance processes	remove SYS PART POSITION	edit	Mar 19, 2021, 4:51 PM	super admin
5.1 Task and responsibilities for Pharmacovigilance processes	up 5.1	edit	Mar 19, 2021, 4:28 PM	super admin
5.2 ICSR collection, collation, follow-up, assessment and reporting	add 5.2	add	Mar 19, 2021, 4:27 PM	super admin
5.1 Task and responsibilities for Pharmacovigilance processes	Add partie 5.1	add	Mar 19, 2021, 4:04 PM	super admin
5. Pharmacovigilance processes	Allow sub section	edit	Mar 19, 2021, 4:02 PM	super admin
3. Safety data sources	update partie 3	edit	Mar 19, 2021, 3:58 PM	super admin
2.4 Links with other organisations	update 2.4	edit	Mar 19, 2021, 3:52 PM	super admin
2.2 Sites where Pharmacovigilance functions are undertaken	update 2.2	edit	Mar 19, 2021, 3:47 PM	super admin

Section	Comment	Action	Date	Author
Abbreviations	remove center style	edit	Mar 19, 2021, 3:31 PM	super admin
3. Safety data sources	update balise	edit	Mar 19, 2021, 3:17 PM	super admin
7. Quality system	add No 8	edit	Mar 19, 2021, 2:44 PM	super admin
6. Pharmacovigilance system performance	add No 6	edit	Mar 19, 2021, 2:44 PM	super admin
5. Pharmacovigilance processes	add No 5	edit	Mar 19, 2021, 2:44 PM	super admin
4.3 Paper data management	add No 4.3	edit	Mar 19, 2021, 2:43 PM	super admin
4.2 Computerised data management	add No 4.2	edit	Mar 19, 2021, 2:43 PM	super admin
4. Computerised systems and databases	add No 4	edit	Mar 19, 2021, 2:43 PM	super admin
3. Safety data sources	add No 3	edit	Mar 19, 2021, 2:42 PM	super admin
2.4 Links with other organisations	add No 2.4	edit	Mar 19, 2021, 2:42 PM	super admin
2.2 Sites where Pharmacovigilance functions are undertaken	add No 2.2	edit	Mar 19, 2021, 2:42 PM	super admin
2. Organisational structure of the marketing authorisation holder	add No 2	edit	Mar 19, 2021, 2:41 PM	super admin
1.5 Local person for Pharmacovigilance	add No 1.5	edit	Mar 19, 2021, 2:41 PM	super admin
1.4 Back-up arrangement	add No 1.4	edit	Mar 19, 2021, 2:41 PM	super admin
1.3 Contact details	add No 1.3	edit	Mar 19, 2021, 2:40 PM	super admin
1.2 QPPV Summary Curriculum vitae	add No 1.2	edit	Mar 19, 2021, 2:40 PM	super admin
1.1 Description of the responsibilities guaranteeing that the QPPV has sufficient authority over the pharmacovigilance system	add No 1.1	edit	Mar 19, 2021, 2:40 PM	super admin

Section	Comment	Action	Date	Author
1. Qualified person responsible for pharmacovigilance (QPPV)	add No 1	edit	Mar 19, 2021, 2:40 PM	super admin
4.3 Paper data management	create partie 4.3	add	Mar 18, 2021, 5:00 PM	super admin
4.2 Computerised data management	create partie 4.2	add	Mar 18, 2021, 4:53 PM	super admin
2.4 Links with other organisations	TEXT REFERENCE DOCUMENT	edit	Mar 18, 2021, 3:51 PM	super admin
4. Computerised systems and databases	allow sub section for section 4	edit	Mar 18, 2021, 3:09 PM	super admin
3. Safety data sources	end of partie 3 edtion	edit	Mar 18, 2021, 3:02 PM	super admin
3. Safety data sources	working progress partie 3 template	edit	Mar 18, 2021, 2:46 PM	super admin
3. Safety data sources	working progress partie 3 template	edit	Mar 18, 2021, 2:43 PM	super admin
2.4 Links with other organisations	add partie 2.4 Links with other organisations template	add	Mar 18, 2021, 2:16 PM	super admin
2.2 Sites where Pharmacovigilance functions are undertaken	add "2.2 Sites where Pharmacovigilance functions are undertaken "	add	Feb 12, 2021, 2:04 PM	super admin
1.3 Contact details	Use EUQPPV ASTREINTE for <ligne astreinte EU QPPV>	edit	Feb 12, 2021, 8:27 AM	super admin
1. Qualified person responsible for pharmacovigilance (QPPV)	update	edit	Feb 12, 2021, 8:22 AM	super admin
2. Organisational structure of the marketing authorisation holder	remove "VAR-LOG"	edit	Feb 9, 2021, 5:09 PM	super admin
1.1 Description of the responsibilities guaranteeing that the QPPV has sufficient authority over the pharmacovigilance system	maj html codes	edit	Feb 9, 2021, 4:40 PM	super admin
1.1 Description of the responsibilities guaranteeing that the QPPV has sufficient authority over the pharmacovigilance system	Update html codes	edit	Feb 9, 2021, 4:36 PM	super admin
PV System master file TEXTE_VAR1_OBLIGATOIRE_NR | Information médicale 2 | Information médicale 3 |	Update "PV System master file"	edit	Feb 9, 2021, 4:20 PM	super admin
Header	set header content empty	edit	Feb 9, 2021, 4:14 PM	super admin

Section	Comment	Action	Date	Author
2. Organisational structure of the marketing authorisation holder	-	edit	Feb 9, 2021, 10:21 AM	super admin
1.1 Description of the responsibilities guaranteeing that the QPPV has sufficient authority over the pharmacovigilance system	ctrl+MAJ+V	edit	Feb 9, 2021, 10:15 AM	super admin
1. Qualified person responsible for pharmacovigilance (QPPV)	MAJ titre	edit	Feb 8, 2021, 3:09 PM	super admin
Header	test	edit	Feb 2, 2021, 1:51 PM	super admin
1. Qualified person responsible for pharmacovigilance (QPPV)	TEXT UM NAME dans titre	edit	Feb 2, 2021, 10:37 AM	super admin
1.4 Back-up arrangement	MAJ	edit	Jan 28, 2021, 12:54 PM	super admin
1.1 Description of the responsibilities guaranteeing that the QPPV has sufficient authority over the pharmacovigilance system	Ajout balise accès médecin quand EUQPPV est client ou presta	edit	Jan 28, 2021, 12:40 PM	super admin
PV System master file TEXTE_VAR1_OBLIGATOIRE_NR | Information médicale 2 | Information médicale 3 |	sup HS	edit	Jan 28, 2021, 12:24 PM	super admin
1.1 Description of the responsibilities guaranteeing that the QPPV has sufficient authority over the pharmacovigilance system	remove table center	edit	Jan 27, 2021, 11:06 AM	super admin
1.4 Back-up arrangement	La texte copier et coller ne marche pas, car il contients des balises html ne support pas par votre liberaire PDF et word	edit	Jan 27, 2021, 10:43 AM	super admin
Footer	La information de la pagination est déjà intégré dans le PDF, et il n'y pas footer pour le document Word	edit	Jan 27, 2021, 10:34 AM	super admin
1.4 Back-up arrangement	Alignement template	edit	Jan 26, 2021, 10:29 AM	super admin
Footer	Ajout numérotation des pages	edit	Jan 26, 2021, 9:40 AM	super admin
PV System master file TEXTE_VAR1_OBLIGATOIRE_NR | Information médicale 2 | Information médicale 3 |	Ajout titre	edit	Jan 26, 2021, 9:35 AM	super admin

Annex I2: History of changes of Annexes in the last 5 years

This table shows different versions of PSMF appendices

Comment	Action	Date	Author
TEST QO	edit	May 26, 2021, 2:50 PM	Baptiste D'Argenlieu

Comment	Action	Date	Author
test QO	edit	Apr 29, 2021, 1:54 PM	super admin
test QO	edit	Apr 29, 2021, 1:49 PM	super admin

Section	Comment	Action	Date	Author
2.1 Description of the marketing authorisation holder organisational structure	TEST	edit	May 25, 2021, 1:54 PM	Baptiste D'Argenlieu
Annex I2: History of changes of Annexes in the last 5 years	formating html code	edit	Mar 25, 2021, 2:21 PM	super admin
Annex H: Products	formatting html code	edit	Mar 25, 2021, 2:14 PM	super admin
Annex F3: Adherence to risk management plan and other obligations or conditions of marketing authorisations To date, SYS_CLIENT_NAME do not have a Risk Management Plan and no obligation or condition in their marketing authorisations.	add LONGTEXT F3	edit	Mar 25, 2021, 2:08 PM	super admin
Annex F3: Adherence to risk management plan and other obligations or conditions of marketing authorisations To date, SYS_CLIENT_NAME do not have a Risk Management Plan and no obligation or condition in their marketing authorisations.	Create "Annex F3:"	add	Mar 25, 2021, 2:06 PM	super admin
Annex D: Computerised systems and Safety Databases	update annex D	edit	Mar 25, 2021, 1:52 PM	super admin
Annex C: Safety data sources	Up "Annex C: Safety data sources"	edit	Mar 25, 2021, 1:11 PM	super admin
Appendix B.1 : List of contracts and agreements	Appendix B.1	edit	Mar 25, 2021, 1:09 PM	super admin
Appendix B : MAH organisational structure	Appendix	edit	Mar 25, 2021, 1:07 PM	super admin
Annex A5. : Information on pharmacovigilance contact person nominated at national level	up	edit	Mar 25, 2021, 1:05 PM	super admin
Appendix B.1 : List of contracts and agreements	Annex	edit	Mar 25, 2021, 11:03 AM	super admin
Appendix B : MAH organisational structure	Annex	edit	Mar 25, 2021, 11:02 AM	super admin
Annex A : EU QPPV	12	edit	Mar 25, 2021, 11:01 AM	super admin
Appendix B : MAH organisational structure	13	edit	Mar 25, 2021, 11:01 AM	super admin
Annex C: Safety data sources	position 14	edit	Mar 25, 2021, 11:01 AM	super admin
Annex D: Computerised systems and Safety Databases	position 15	edit	Mar 25, 2021, 11:00 AM	super admin
Annex E: Pharmacovigilance processes and written procedures	change position from 15 to 16	edit	Mar 25, 2021, 11:00 AM	super admin
Annex F: Pharmacovigilance system performance	change position from 16 to 17	edit	Mar 25, 2021, 10:59 AM	super admin

Section	Comment	Action	Date	Author
Annex G: Quality system	position from 18 to 19	edit	Mar 25, 2021, 10:58 AM	super admin
Annex H: Products	position from 18 to 19	edit	Mar 25, 2021, 10:58 AM	super admin
Annex I: Document and record control	position from 19 to 20	edit	Mar 25, 2021, 10:58 AM	super admin
2.3 Delegated activities relating to the fulfilment of pharmacovigilance	LONGTEXT PRESTA SERVCES	edit	Mar 24, 2021, 8:36 AM	super admin
2.3 Delegated activities relating to the fulfilment of pharmacovigilance	update partie 2.3	edit	Mar 22, 2021, 2:53 PM	super admin
4.1 Pharmacovigilance Computerized Database	Disable sub section	edit	Mar 22, 2021, 12:56 PM	super admin
2.1 Description of the marketing authorisation holder organisational structure	disable sub section	edit	Mar 22, 2021, 12:56 PM	super admin
4.1 Pharmacovigilance Computerized Database	r	edit	Mar 19, 2021, 4:53 PM	super admin
2.3 Delegated activities relating to the fulfilment of pharmacovigilance	r	edit	Mar 19, 2021, 4:53 PM	super admin
2.1 Description of the marketing authorisation holder organisational structure	r	edit	Mar 19, 2021, 4:52 PM	super admin
2.1 Description of the marketing authorisation holder organisational structure	insert LONGTEXT DESCRIPTION MAH	edit	Mar 19, 2021, 3:37 PM	super admin
4.1 Pharmacovigilance Computerized Database	add No 4.1	edit	Mar 19, 2021, 2:43 PM	super admin
2.3 Delegated activities relating to the fulfilment of pharmacovigilance	add No 2.3	edit	Mar 19, 2021, 2:42 PM	super admin
2.1 Description of the marketing authorisation holder organisational structure	add No 2.1	edit	Mar 19, 2021, 2:41 PM	super admin
4.1 Pharmacovigilance Computerized Database	partie 4.1	add	Mar 18, 2021, 4:08 PM	super admin
2.3 Delegated activities relating to the fulfilment of pharmacovigilance	update partie 2.3 template	edit	Mar 18, 2021, 2:01 PM	super admin
2.3 Delegated activities relating to the fulfilment of pharmacovigilance	working progress partie 2.3	add	Mar 18, 2021, 11:06 AM	super admin
2.1 Description of the marketing authorisation holder organisational structure	Update the content from PSMF template	edit	Mar 18, 2021, 10:22 AM	super admin
Annex I2: History of changes of Annexes in the last 5 years	update	edit	Feb 12, 2021, 6:20 PM	super admin
Annex I1: Logbook - Change on Main Body in the last 5 years	update	edit	Feb 12, 2021, 6:19 PM	super admin
Annex I1: Logbook - Change on Main Body in the last 5 years	update	edit	Feb 12, 2021, 6:18 PM	super admin

Section	Comment	Action	Date	Author
Annex I2: History of changes of Annexes in the last 5 years	HISTORIQUE VESRION PSMF ANNEXES MOINS 5ANS bug	edit	Feb 12, 2021, 4:20 PM	super admin
Annex I1: Logbook - Change on Main Body in the last 5 years	HISTORIQUE VESRION MAIN BODY MOINS 5ANS bug	edit	Feb 12, 2021, 4:20 PM	super admin
Annex I2: History of changes of Annexes in the last 5 years	remettre HISTORIQUE VESRION PSMF ANNEXES MOINS 5ANS	edit	Feb 12, 2021, 3:47 PM	super admin
Annex I1: Logbook - Change on Main Body in the last 5 years	reset HISTORIQUE VESRION MAIN BODY MOINS 5ANS	edit	Feb 12, 2021, 3:46 PM	super admin
Annex E4: Lists of NAME OF THE OTHER PV SUBCONTRACTOR procedural documents	not user <> balise without close	edit	Feb 12, 2021, 3:31 PM	super admin
Annex I2: History of changes of Annexes in the last 5 years	update	edit	Feb 12, 2021, 8:18 AM	super admin
Annex G1.: List of audits performed in the last 5 years (updated yearly)	update	edit	Feb 11, 2021, 7:50 PM	super admin
Annex G: Quality system	update	edit	Feb 11, 2021, 7:49 PM	super admin
Annex E4: Lists of NAME OF THE OTHER PV SUBCONTRACTOR procedural documents	maj	edit	Feb 11, 2021, 5:36 PM	super admin
Annex I2: History of changes of Annexes in the last 5 years	HISTORIQUE VESRION PSMF ANNEXES MOINS 5ANS pose de problème	edit	Feb 11, 2021, 5:26 PM	super admin
Annex I1: Logbook - Change on Main Body in the last 5 years	HISTORIQUE VESRION MAIN BODY MOINS 5ANS pose de problème	edit	Feb 11, 2021, 5:25 PM	super admin
Annex E1: Lists of SYS_CLIENT_NAME procedural documents	remove	edit	Feb 11, 2021, 2:50 PM	super admin
Annex E1: Lists of SYS_CLIENT_NAME procedural documents	remove bla bla text	edit	Feb 11, 2021, 2:46 PM	super admin
Annex D: Computerised systems and Safety Databases	add IMG UM COMPUTER SYS	edit	Feb 11, 2021, 1:56 PM	super admin
Appendix B : MAH organisational structure	remove "bla bla"	edit	Feb 11, 2021, 12:44 PM	super admin
Annex A5. : Information on pharmacovigilance contact person nominated at national level	LONGTEXT A5 PAYS not LONGTEXT A6 PAYS	edit	Feb 11, 2021, 10:48 AM	super admin
Annex A3: Contact details of the EU QPPV	update to the version of 05-01-2021	edit	Feb 11, 2021, 9:50 AM	super admin
Annex A1.: EUQPPV curriculum vitae	maj à 05-01-2021	edit	Feb 11, 2021, 9:37 AM	super admin

Section	Comment	Action	Date	Author
2.1 Description of the marketing authorisation holder organisational structure	Notre libreraire PDF support que simple html, <p>, , <table>, , <b>, <color>, pas des balises et des fonts spéciaux,	edit	Jan 27, 2021, 10:49 AM	super admin
2.1 Description of the marketing authorisation holder organisational structure	Ajout titre	edit	Jan 26, 2021, 3:52 PM	super admin
2.1 Description of the marketing authorisation holder organisational structure	MAJ	edit	Jan 26, 2021, 11:22 AM	super admin
2.1 Description of the marketing authorisation holder organisational structure	Création	add	Jan 26, 2021, 11:14 AM	super admin