Centrality

A total solution for XEVMPD compliance - and beyond

- Easy-to-use software plus key services
- Created & delivered by regulatory professionals
- Fast route to meeting e-reporting requirements
- Future-proof solution for product data submissions

Your solution partner for EVMPD submissions

We provide a comprehensive EVMPD and Article 57 (2) compliance solution for Marketing Authorisation Holders. Our Centrality software tool has been designed by regulatory affairs experts to enable you to quickly and easily submit information to the EVMPD. Centrality allows pharmacovigilance teams to effortlessly convert existing medicinal product information into an XML Schema Definition (XSD)-compliant format, and seamlessly upload the required data as a EudraVigilance Product Report Message (EVPRM) using an approved submission mechanism. The system enables the creation of a complete, centralised product information database for future use, and provides integrated, intuitive capabilities for managing ongoing updates to product data.

A complete solution: Key Support Services

The Centrality solution can be coupled with our Key Support Services to ease the administrative burden and enable Marketing Authorisation Holders to extract maximum value from collected substance data.

Our expert team of qualified chemists can provide data collation, data entry and data checking services, including fully outsourced data-gathering and the compilation of complete Structured Substance Information (SSI) libraries.

A complete XEVMPD compliance solution

Centrality software

Designed by RA experts

Secure, easy-to-use, standards-compliant

Transparent pricing options

Flexible deployment cloud, intranet or standalone access

Key Support Services

Delivered by qualified chemists

MA data collation & entry

Full SSI library compilation

Custom software integration interfaces

Centrality software platform

Our Centrality software platform delivers a comprehensive solution and complete product license database for managing pharmacovigilance data updates and ensuring continuing EMA regulatory compliance and adherence to Article 57 (2) of Regulation (EC) 726/2004. The Centrality software is secure, easy to use and custom-engineered for flexible implementation.

Uniquely flexible and intuitive system.

Centrality enables authorised users to securely upload XML Schema Definition (XSD)-compliant product data, efficiently track compliance activity, and create a valuable centralised product information database for future use. Centrality offers a full feature set, including:

- *Ease of use follows the flow of the XML specification*
- *Data checking data validation on entry and on submission*
- *Intuitive change tracking user alerts for cross-system updates*
- *Document change tracking synchronised with current version control mechanisms*
- *Robust audit trail automatic logging of all user activities*
- *Centralised database supports product life cycle management*
- *Data security user-defined access levels*
- *Data protection redundant secure data servers*
- *Legacy system integration full harmonisation with existing systems*
- *Future-proofing data abstraction for ongoing standards compliance*
- *Flexible deployment options secure cloud, on-site intranet or standalone application*

Easy data checking

Data checking is based on the XML Schema and is performed at two points: firstly, at the point of data entry during form completion, where on-screen interactive helpers will notify users of any data entry issues; and secondly, at the time of form submission data is checked on upload into the database tables during both interactive and batch processing.

Intuitive change tracking

When an EVPRM message is created by the system, a record of all the elements is stored. For subsequent updates to any data element used in previous EVPRMs (for example, changes to part of an organisation's address), the system will automatically re-generate these EVPRMs and a user alert will provide the option to submit these messages as updates to the EMA.

Assured document control

Centrality offers full integration with your existing document tracking and version control mechanisms. The system automatically notifies users if any referenced documents have been updated and provides the facility for users to upload the revised data or attachment and re-submit the message.

User-defined access & status levels

Centrality offers prioritised user access and information status levels throughout all system processes. User access can be defined to control which operations individual users can and cannot perform (for example, data entry, editing of existing entries, approval, submission and so on).

Similarly, the system operates clear controls for the status of each data element - 'Draft', 'complete', 'Approved' - and provides full cross-referencing capabilities, including the ability to list which data elements have been used in EVPRMs. Centrality also tracks the system activity of each individual user in the system - logging every update by user and date.

Optimised data entry

To ease the process of submitting data gathered from existing sources and entering it into the software, we offer a choice of 3 data entry options:

Simple fill-form: you can enter your Marketing Authorisation (MA) data sequentially, completing each section as needed. This solution follows the XML specification and documentation and is optimal for organisations submitting a small number of MAs (fewer than 10).

Library-oriented entry: our software offers the ability to build a structured library of core data elements, to be re-used multiple times to create multiple derivative MAs (for example, 'Organisation', 'Attachment', 'Source', 'Substance data'). This option works best for organisations with similar data to be entered into a large number of different MAs.

Batch import: we provide the facility to import XML or Excel files into our system. This method makes it easy to quickly incorporate data from legacy systems, and to create similar records from spreadsheet-format data.

Accessing the software

Centrality is available as an on-demand cloud-based application (Software-as-a-Service) accessed via a standard web browser or as a standalone software application.

Centrality can be installed on your company intranet, so that the data is held on-site and authorised users can access it securely via the company system. We offer transparent pricing for all service package options, and provide complete, inclusive support for Windows and Linux operating systems.

Centrality software: core features

Ease of use

Assured data validation, integrity & security

Flexible data entry options

Intuitive change tracking

Robust audit trail

Future-proof standards compliance

Flexible deployment

Windows & Linux compatible

Business benefits

Reduce admin seamlessly convert existing product data

Comply securely fast upload via an approved mechanism

Track activity electronic audit trail for managing compliance

Centralise data complete product license and information database

Engage flexibly transparent pricing for on-demand or on-site installation

Key Support Service

Full service solution

Our uniquely flexible software solution can be supported by our highly skilled service organisation of qualified chemists and access to our key SSI library resources. Our specialist Key Support Services teams can reduce the admin burden of collating, organising, validating and submitting key substance information.

What we can provide

We can provide a fully-outsourced EVMPD compliance service including:

- *Element Library Compilation service*
- *Full compilation service harnessing our Element SSI library of excipients and active ingredients*
- *Conforms to the EMA's Controlled Vocabularies guidelines*
- *Data gathering*
- *A team of qualified chemists to collate key MA information*
- *Data entry*
- *Data validation and submission by highly trained personnel*

We also offer bespoke software integration development support to help gather data from across your network and provide full harmonisation with your existing systems.

We can help: request a Centrality demo

To talk to us about your specific system requirements and how we can deliver a full software solution, expert services, and a fast, secure route to EVMPD and Article 57 (2) compliance, please contact us.

www.pharmaereport.com/centrality