The Development of a Quality Assurance Signal Analytics Framework

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Background: The concept of regulatory science has been coined to provide scientific knowledge and intelligence for informed decision-making by regulatory, statutory and jurisdictional bodies. The contemporary upsurge of regulatory sciences, transnational pharmaceutical markets, advanced healthcare technologies and the cumulative intricacy of supply chain networks has emphasised the need for collaborative interfaces amongst regulatory agencies, systems and infrastructure.

Objective: Development of a Quality Assurance Signal Analytics Framework (QASAF).

Methodology: Quality improvement forms (QIFs) were systematically analysed, and data was consolidated in a tabulated format, featuring four criterion-based rows: QIF reference number, root cause identification, listing of positive and negative signals along corresponding principles, and assignment of Likert scale values. Signals were aligned with principles inspired from established frameworks, such as ISO9001. A four-column criterion framework guided the selection of relevant principles, encompassing the organisational quality assurance ethos, thematic principles, characteristics, and Likert scale integration.

Results: The QASAF is constituted of two components: the Systematic Quality Signal Extraction Framework (SQSEF) for data analysis and the Principle–Based Signal Alignment Framework (PBSAF) for thematic analysis and integration of the Likert psychometric scale. This dual-structured tool facilitates the systematic extraction and alignment of quality signals within regulatory contexts.

Conclusion: The QASAF utilises the element of the signal as a mechanism to direct conscious effort throughout the evaluation process, thereby ensuring an evidenced-based approach. The QASAF serves as a visual and analytical tool for researchers and regulatory professionals in navigating pharmaceutical regulatory signals. This framework supports the identification of organisational opportunities and risks, ultimately contributing to informed decision-making and enhanced regulatory practice.