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The Development of a Quality Assurance Signal Analytics Framework

Project brief

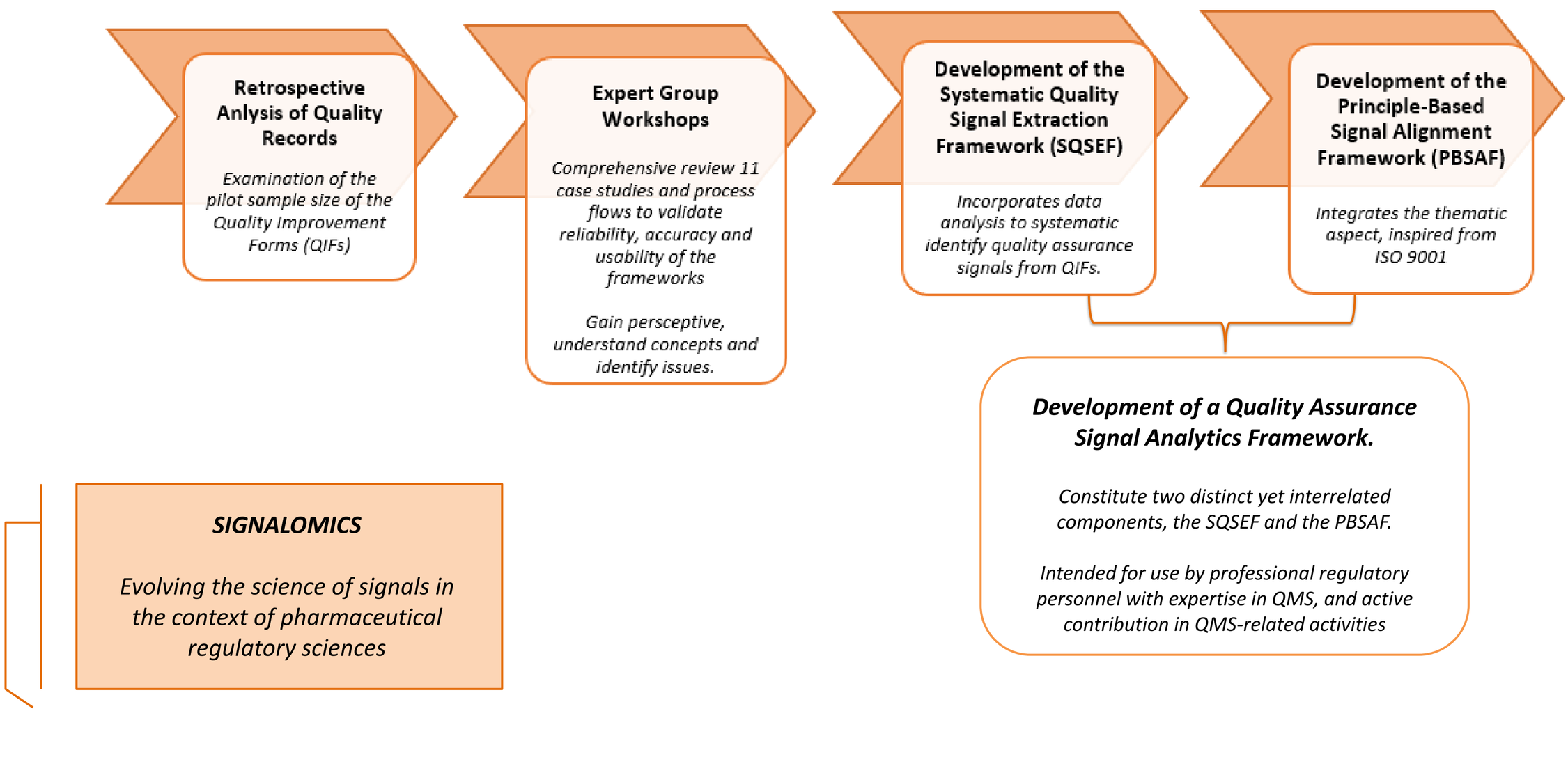
Aims

In an increasingly interconnected pharmaceutical landscape, the concept of regulatory science is more vital. Far beyond compliance, regulatory science serves as a strategic intelligence core, enabling informed decisions. This evolving landscape underscores a critical need to support the development of a harmonised system for the management of quality assurance signals within medicinal products regulatory sciences.

Objective

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

Methodology



Results

The QASAF is shown to:

- Facilitate an empirical evaluation and classification of the identified quality assurance signals through a data-driven analysis approach, SQSEF.
- Incorporating a thematic dimension into the identified quality assurance signals, through application of the PBSAF.
- Support trend analysis to specify the most prominent themes and thematic principles, providing insights into the organisational cultural ethos in relation to quality management practices.

Conclusions

The QASAF utilises the element of the signal as a mechanism to direct conscious effort throughout the evaluation process, supporting an evidenced-based approach. In vein of the study signals for quality assurance in pharmaceutical regulatory sciences are in its infancy, so more when signals are considered in quality management systems.