

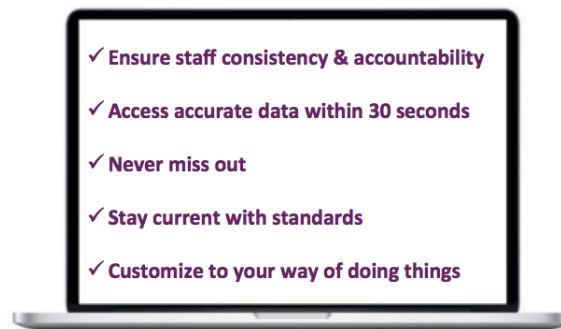
CompoundingQMS™ User Requirements

Innovative OncoSolution's CompoundingQMS™ product offering is the result of years of experience in pharmacy audit and quality control and was built from the ground up as a totally electronic cloud-based audit and quality assurance system.

CompoundingQMS™ is the first and most customizable cloud-based solution incorporating best practices that address multiple quality, safety and compliance challenges of pharmacies. It replaces inefficient paper & spreadsheet compliance programs and less customizable web-based tools. The platform addresses all NAPRA guidelines including:

- ✓ **USP 797/ 800/ NAPRA compliance**
- ✓ **Drug Diversion**
- ✓ **Medication Storage**

Implementation is easy and straightforward. Whether it be self-audits, environmental monitoring and competency tracking for USP Chapters 797/ 800 and NAPRA, detection and prevention of drug diversion, tracking URAC compliance or ensuring safe and proper medication storage – clients can implement and start using CompoundingQMS™ in less than a week. No IT integration or support is required.



To assist in any Consulting Services and support as it relates to NAPRA compliance, IOS has a deep and close business relationship with Visante Canada, the premier pharmacy consulting company in Canada. IOS is able to bring the experience of Visante's global pharmacy experts in USP 795, 797, 800, cGMP and NAPRA together to support any compliance issues related to these standards.

IOS offers a breadth of NAPRA expertise in design layout and we can also offer suggestions on your current workflow as it relates to NAPRA. We have been working with dozens of other hospitals engaged in NAPRA compliance and can share with you the rationale and decisions on how they have moved forward.

At a minimum, when looking at a NAPRA compliant Quality Management System solution, the following Mandatory and General Requirements should be evaluated:

MANDATORY REQUIREMENTS

A Quality Management System that includes a component that enables compliance with personnel requirements on NAPRA Model Standards for Pharmacy Compounding (Hazardous and Non-Hazardous)

Training modules that are aligned with NAPRA Standards

A Quality Management System that includes a component that enables compliance with policies and procedures requirements on NAPRA Model Standards for Pharmacy Compounding (Hazardous and Non-Hazardous)

All policies and procedures are aligned with NAPRA standards

A Quality Management System that includes a component that enables compliance with general maintenance log requirements on NAPRA Model Standards for Pharmacy Compounding (Hazardous and Non-Hazardous)

A Quality Management System that includes components for cleaning and disinfecting / certification and maintenance of facility as a whole / certification and maintenance of the pEC and CPEC / maintenance of other equipment / verification of proper operation of equipment and instruments (calibration, refrigerator, temperatures, etc.)

A Quality Management System that includes a component that enables compliance with quality assurance program on NAPRA Model Standards for Pharmacy Compounding (Hazardous and Non-Hazardous)

All quality management system elements are aligned with NAPRA standards

GENERAL REQUIREMENTS

A Quality Management System that includes components that enables compliance with product and preparation requirements on NAPRA Model Standards for Pharmacy Compounding (Hazardous and Non-Hazardous)

A Quality Management System that can be modified to meet changes in Canadian standards in a timely manner

A Quality Management System that meets or exceeds Canadian Society of Hospital Pharmacists (CSHP) Compounding: Guidelines for Pharmacy, 2015

A Quality Management System that includes detailed educational / learning modules in terms of how training is accomplished (i.e., interactive slides, videos, tests, etc.)

A Quality Management System that has the ability of the system to be customized to meet needs of the facility

A Quality Management System that Administrators can access remote locations centrally (enterprise solution)

A Quality Management System to enable compliance with NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations

Ability to restrict user access control and permissions. User definable access control to limit access at organization, department, user, system, function, and file levels.

A Quality Management System that has the ability to:

- Create Tasks and/or Alerts & Real-Time Alerts
- Assign & Prioritize Tasks
- Assign Follow Up Tasks
- Trace Electronic Signature
- Create Reports & Statistics

A Quality Management System that offers tracking of training

A Quality Management System that provides for training new staff post go-live