

A male scientist with short, dark hair and a beard, wearing a white lab coat over a blue shirt and tie, is looking down at a tablet computer. He is in a laboratory setting, with a microscope on the left and a rack of test tubes on the right. Some test tubes contain red liquid. The background is bright and slightly out of focus.

WellSky Quality & Compliance

Complete document, competency, and accreditation management for cellular therapy programs.

Solutions for realizing care's potential



WellSky Quality & Compliance is an easy-to-use, web-based solution that simplifies and streamlines document, training, compliance, and accreditation processes for cellular therapy, regenerative medicine, and bone marrow transplant programs.

The system can function as a complete integrated solution or fill in the gaps where broader enterprise-wide solutions fall short in meeting the regulatory requirements mandated by compliance and accreditation agencies. WellSky Quality & Compliance also integrates with WellSky Biotherapies solutions as well as human resource and enterprise learning management solutions.

- **Simplicity**
Everything you need is organized in an easy-to-use system that requires virtually no end-user training.
- **Efficiency**
Streamlining change management, simplifying document versioning, automating assignment follow-up, and eliminating repetitive and error-prone tasks are just some of the ways WellSky Quality & Compliance improves efficiency.
- **Mitigation**
A comprehensive and organized system that clearly communicates status and required actions, as well as proactively escalates and follows up, is the most effective way to ensure compliance on an ongoing basis.
- **Clarity**
Online processes, reminders, task queues, and compliance dashboards provide a clear picture of where you stand and what needs to be done.
- **Organization**
Bundling related SOPs, training, and competencies by task or theme; associating requirements by job or department; and linking documents and attestations to AABB, FACT, and other checklists ensures that requirements are met and accreditations maintained.
- **Improvement**
With these results, your organization will improve its quality and efficiency as well as employee and client satisfaction.

Designed to meet regulatory requirements for BMT, regenerative medicine, and cellular therapy

WellSky Quality & Compliance was designed specifically to help facilities meet the complex quality, compliance, accreditation, and document management requirements of their cellular therapy, regenerative medicine, and transplant programs. Even programs that are part of large health systems find that hospital-wide solutions were not designed with AABB, FACT, CAP, and FDA requirements in mind.

As a result, many CT and BMT programs struggle with spreadsheets and homegrown or manual systems in an attempt to keep up. Given the constantly increasing level of complexity, it is just a matter of time before something falls through the cracks.

WellSky brings everything together in one system, incorporating the linkages between SOPs, competencies, and checklists. This helps you easily and efficiently manage compliance and accreditation.

Document management

- Save source documents, with complete version control and change tracking
- Review and approve documents online
- Automate document publishing and deployment
- Create virtual online document binders with access controls and full-text search
- Automate management of annual/ biennial regulatory review
- Utilize flexible online workflows, and capture CFR 21 Part 11 compliant electronic signatures
- Automatically synchronize offline document master copies to designated PC's to overcome network outages and meet FDA requirements.

Accreditation management

- Import CAP, AABB, FACT, and other checklists
- Create and schedule audits based on checklists
- Link SOPs and other attestation to checklist items
- Assign and track checklist items
- Automatically update checklist linkages as document revisions occur
- Automate audit updates with new checklist versions (with prior history retained)

Competency and learning management

- Task-based and theme-based requirements management
- Schedule and track documents, training assignments, and competency assessments
- Attach evidentiary documentation
- Track staff credentials and certifications
- Automate reminders and status reports

Change management

- Route change request submissions
- Communicate reasons for change and impact assessments
- Link affected documents
- Review and approve changes online
- Schedule and track changes
- Deploy affected documents automatically



Improves quality and efficiency while mitigating risk

Through the integration of document, accreditation, and competency management, combined with the application of LEAN concepts and computer information technology, WellSky addresses the unique requirements of cellular therapy and transplant programs as smoothly and efficiently as possible.

Requirements bundling:

Group SOPs, job aids, training, competencies, and other requirements by task (such as red cell reduction) or theme (such as stem cell processing) to greatly reduce the time, effort, and complexity of requirements management.

Job profiles:

Assign bundles and individual requirements by job profiles, so you can completely automate requirements management. As employees come on board or change roles, requirements and assignments adjust automatically.

Version management:

WellSky makes this process easy and efficient. Simply check out documents, make your changes, and check the documents back in. Then click "Publish for Review" or "Publish for Approval." Documents are automatically assembled with system-generated cover sheets, instructions, and change history and then routed to the appropriate reviewers or approvers.

Task queue:

The task queue provides a single location for reviewers, approvers, and other contributors to access and complete document management tasks. Tasks are presented in prioritized order, with all necessary information immediately available.

Online review and approval:

Document managers can monitor progress and see additional details, such as workflow status, for individual documents. Once approved, documents are automatically published for distribution.

Approval history forms are automatically generated and attached, and client-defined headers, footers, watermarks, and access rights are applied.

Online document deployment:

Once documents are published for distribution, revised items are deployed with just a few clicks. Online binders, accreditation linkages, and job requirements are updated automatically, and new assignments are generated for the appropriate staff.

Accreditation management:

FACT, CAP, and similar checklists are imported with just a few clicks. Checklists are then easily assembled into audits, and checklist items are assigned for completion. SOPs, policies, and other documents, as well as free text entries, are linked to checklist items as attestation of compliance and then automatically routed for electronic approval.

By automating these tasks, the process can be completed in a fraction of the time it takes to do manually. As documents are revised, the linkages to checklist items are updated. Similarly, when new versions of checklists are imported, KnowledgeTrak automatically detects changes, deletions, and additions and flags those items for review while maintaining all prior associations.

Intuitive monitoring and reminding:

WellSky Quality & Compliance monitors all tasks, requirements, and activities and proactively reminds and escalates as necessary to ensure everything is up to date and completed on time. Because the system is so intuitive and easy to use, no end-user training is required.



Integrated, easy to use, and quick to deploy

WellSky Quality & Compliance also integrates with WellSky Biotherapies and other WellSky clinical applications, making additional features available. It also integrates with enterprise information systems, allowing it to automatically adjust users' requirements as their status or job positions change.

Integration with WellSky Biotherapies and other WellSky clinical products

Through WellSky Biotherapies menu, users can easily:

- Open and complete assignments, including WellSky Biotherapies online product training
- Browse, search, and review online documents and binders
- Access and complete electronic approvals and alerts
- Review and approve document changes

In addition, when users first login to WellSky Biotherapies, the system verifies that each user is current on the competencies and training required to operate the system. If not current, the user is either warned or locked out of WellSky Biotherapies until requirements are completed. Once logged in, WellSky Biotherapies users see the status of their assignments, tasks, and alerts in the WellSky Biotherapies status bar. This information is constantly updated, letting them know when action is required.

Integration with other systems

WellSky Quality & Compliance also interfaces with Active Directory (AD) for user account management and authentication. The system can automatically create and disable accounts and update account information as it is updated in AD. When your HRIS is interfaced with AD, WellSky Biotherapies can automatically move users to new groups, update job profiles, and manage assignments accordingly.

Easy to use and quick to deploy

The system's design is simple, clean, and intuitive, so end-user training is not required. An email welcomes new users to the system and provides a link to their pending assignments. A short tutorial teaches the basics in a few minutes' time.

Flexible and configurable

WellSky Quality & Compliance is installed at hundreds of sites, none of which have required customization. The system can easily be configured by customers or our support staff to meet specific requirements. Virtually all configuration is done via user-friendly screens.

Since WellSky Quality & Compliance is entirely web-based and designed specifically for healthcare, the system requires no special client software and is quickly and easily deployed. The benefit to customers is simplified validation, more rapid implementation, and freedom to upgrade without future customization fees.



Get started today!

Contact your WellSky representative to learn more or schedule a demonstration.

1-855-wellsky

