The FDA is Prioritizing Knowledge Management. Get Ready for KASA.

The FDA is rolling out a new system to capture and manage drug approval information to make regulatory oversight better. What does this mean for big pharma?

The U.S. Food and Drug Administration (FDA) Pharmaceutical Quality for the 21st Century Initiative is still in full swing after more than a decade and several manufacturing quality successes.

What's next on the agenda? A new quality assessment system which aims to standardize drug product review submissions in a new, easier format.

Structured knowledge management is essential

The FDA recognizes that the world is accelerating. Pharma companies are submitting a huge number of applications with short deadlines, and the FDA is struggling with the workload. Instead of extending response times, the FDA did an efficiency review and found several issues with its current quality assessment.

1. FDA reviewers have trouble finding relevant historical data to compare an application against, which causes bottlenecks.
2. Current submissions are mostly narrative and unstructured which opens the door for regulatory inconsistency and redundancy.

In September 2018, the FDA admitted that the current system is a solution for a 20th century process when reports were still mostly submitted on paper. The time for modernization is here - and that means moving from unstructured text-based knowledge and lifecycle management to structured reporting.

The key for big pharma is that the FDA is creating a new interface to receive submissions - this means that pharma companies will have to comply with the new format.

Since many details are still up in the air, moving to a structured knowledge management system is the best way to prepare for KASA, whatever the new format will be.

How does KASA work?

KASA (Knowledge-aided assessment and structured applications) is the natural evolution of the

current eCTD format optimized for the 21st century. It tracks the drug development cycle better than eCTD and gets rid of unstructured data, making information consistent across submissions. This gives the FDA more clarity and better risk mitigation and speeds up the review process.

At a high level, the FDA will set rules and algorithms which it can use to standardize review and capture risk early-on. Better risk management upfront will reduce the iterations needed to reach approval, and because each submission will arrive in a standardized format, reviewers will be able to automate redundant work and pull better historical data.

The details of the exact KASA infrastructure are still unknown, but stated goals as of 2018 are:

- To review applications more efficiently.
- To spot information gaps and deficiencies earlier.
- To manage knowledge across all aspects of the review

  process (including pulling in the right historical data for comparison).
- To track product quality and risk throughout the entire lifecycle.
- Deliver consistent and predictable analysis.
- To automate analysis of portions of the application.

The FDA is enthusiastic about the initiative, marking $30M in funding in FY2019-FY2020. But there are still many questions to be answered.

Will branded drug applications need to be in KASA format, or just generics?

How long until KASA is fully implemented?

Luckily, there's no need to wait for answers. Pharmacos can start preparing now.

What can pharma companies do to prepare for KASA?

Right now, only generics are being considered for KASA but generics aren't likely to be the end. Pharma companies need to be proactive given KASA's support and unclear implementation details.

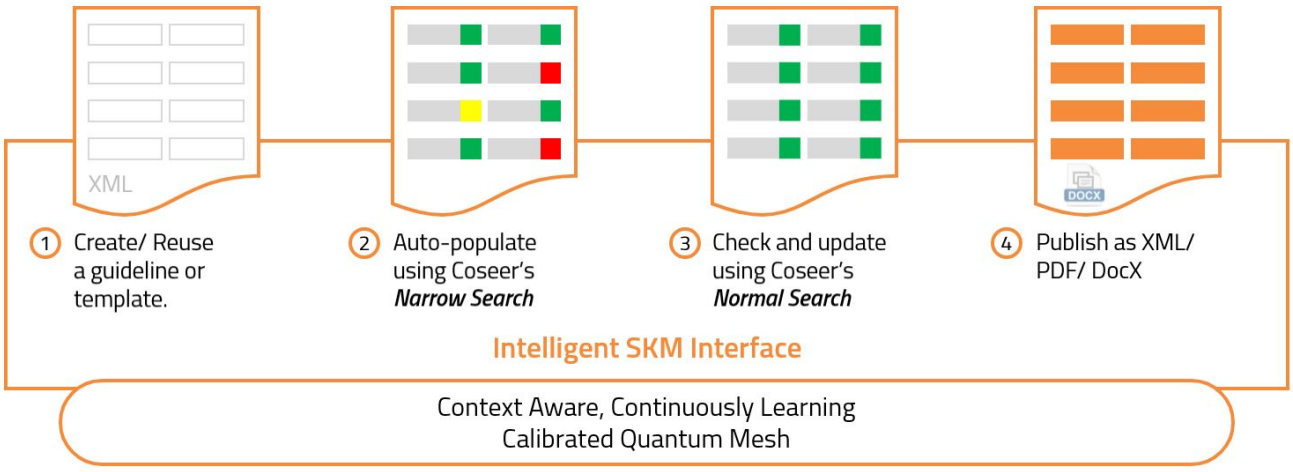
KASA or not, the time has come for big pharma to embrace structured knowledge management. It's a powerful tool for efficient operations, and now it's a competitive advantage as well -giving an edge over companies still slogging through unstructured text-based documents.

Drug approval submissions that are complete, transparent, and easy for the FDA to process will get approved faster and go to market faster. It's as simple as that.

How can I make the move to structured knowledge management?

With NLS-based AI, moving from unstructured to structured knowledge management can be easy. Coseer's unique algorithm, Calibrated Quantum Mesh, can do the heavy-lifting so your team can focus on getting the science right before submission.

1. Create/reuse a guideline or a template including key data elements and terminologies you'll need to include. The FDA is working on a standard set of these right now.
2. Auto-populate using Coseer's Narrow Search, which focuses on getting the best answer. Specific answers are returned with high confidence.
3. Check the results from Narrow Search and update using Coseer's Normal Search. The focus here is on helping the user by finding helpful content. Human interaction is required to learn and becomes more helpful over time.
4. Publish as XML/PDF/DocX. This can be done automatically by Coseer based on your template, so no need to assemble the report on your own.



We've worked with top-20 pharma companies to modernize their knowledge management, and we can do the same for you.

With Coseer, KASA is an amazing opportunity to get ahead, not a regulatory roadblock. For a quick summary of what's been discussed here, check out our video on KASA, or Setup a call with our team to learn more.

What is Next-Generation Enterprise Search?

Coseer's search solutions are transforming industries from healthcare to finance. Our point-and-shoot AI trains finds answers and insights with 95%+ accuracy within 4-12 weeks - all of this in 100% security. The reason? We founded Coseer on the principle that computers should take care of the boring stuff so that humans can focus on creativity and judgment. To that end, we've built enterprise search solutions to complete complex workflows just as humans would in a fraction of the time. Fortune 500 leaders are using Coseer to speed up and automate their most complex work.

We follow a tactical approach to enterprise search:

- We deliver 95-98% accurate solutions within 4-12 weeks.
- Our solutions deploy entirely behind your own firewall for 100% security, and every decision point is logged for full transparency.
- You add the finishing touches, but our point-and-shoot AI practically trains itself. No more huge training data sets or time wasted annotating and tagging.

Visit our website for in-depth case studies, ROI breakdowns per industry, and other insight.