



Scaling GenAI in Regulated Clinical Document Generation

Lessons from Hundreds of Trials

Emmanuel Walckenaer, CEO of Yseop
March 2026





Regulatory-grade AI for Life Sciences

A global team of **100+** across **France & the US**
combining AI and Life Science expertise
Clients include **1/3 of the world's top pharma**

Proven in production across 300+ clinical trials

B\$ in accelerated revenue by cutting months from submission timelines

GSK

sanofi

 **NOVARTIS**

PPD

Lilly


LABORATOIRES
Pierre Fabre

Regulatory-grade AI

Accurate

Repeatable

Traceable

Submissions approved by



EUROPEAN MEDICINES AGENCY
SCIENCE · MEDICINES · HEALTH

Lesson 1

Scaling requires more than an LLM



Drafting

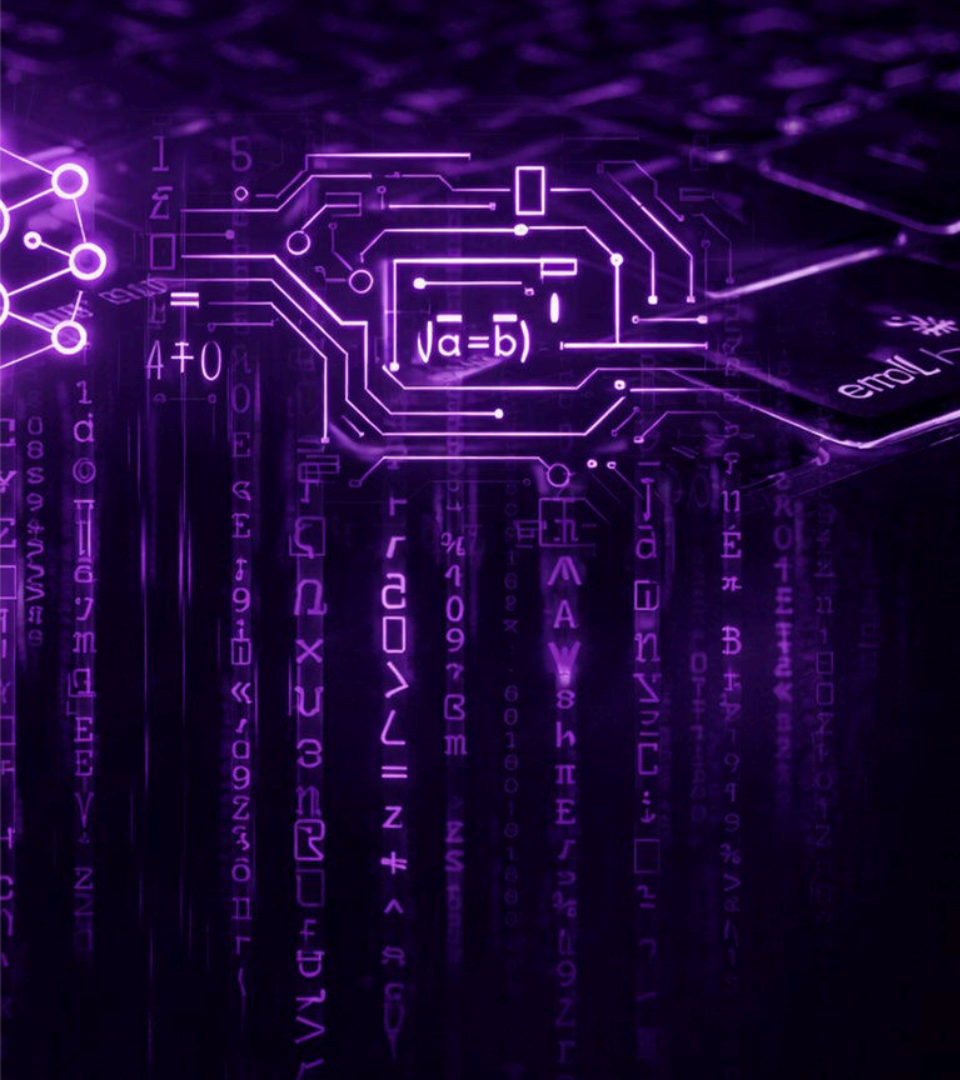


Predictable



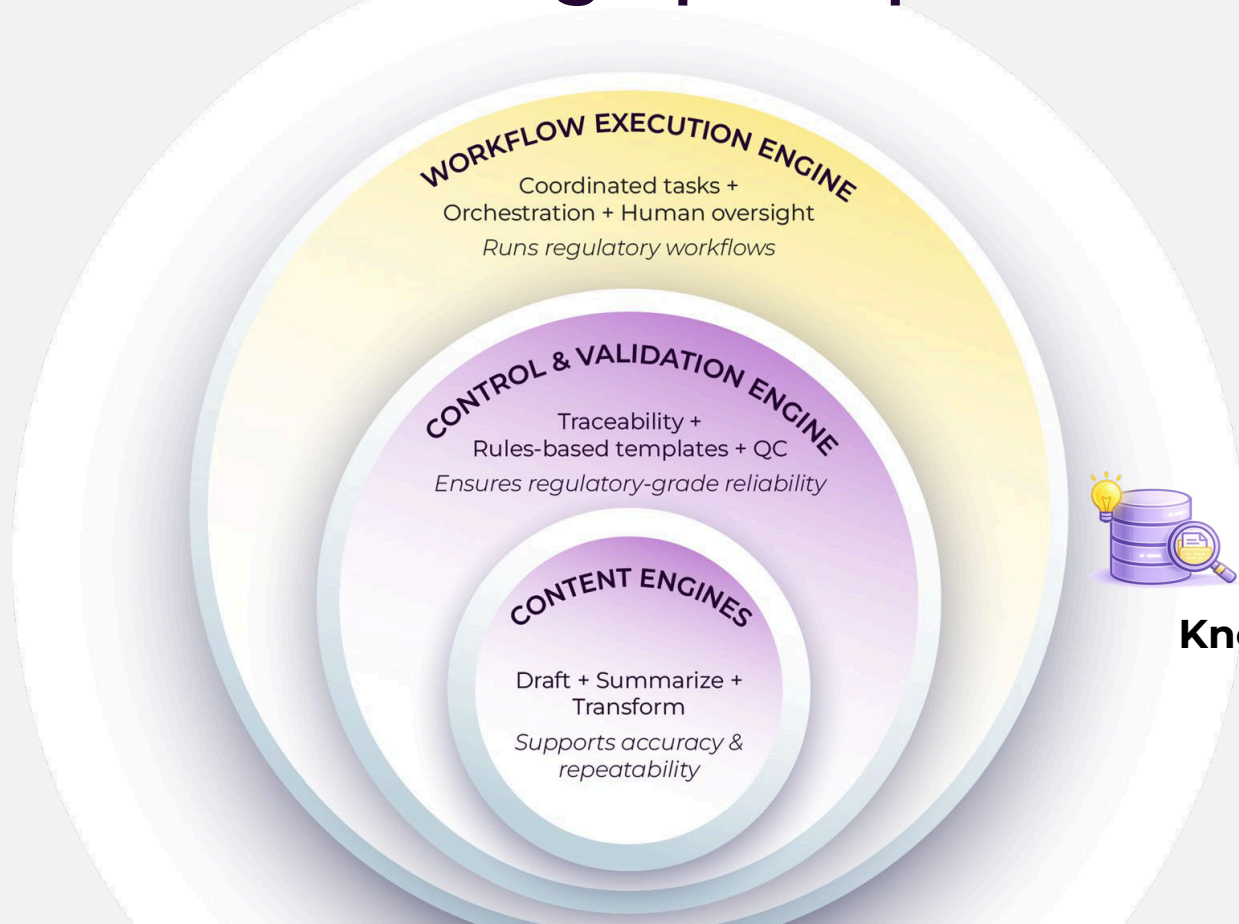
Accurate



e



Neuro-Symbolic AI for regulatory-grade reliability

Trust as a design principle.



-  AGENTIC = AI AGENTS
-  NEURO-SYMBOLIC =
GENAI + SYMBOLIC AI



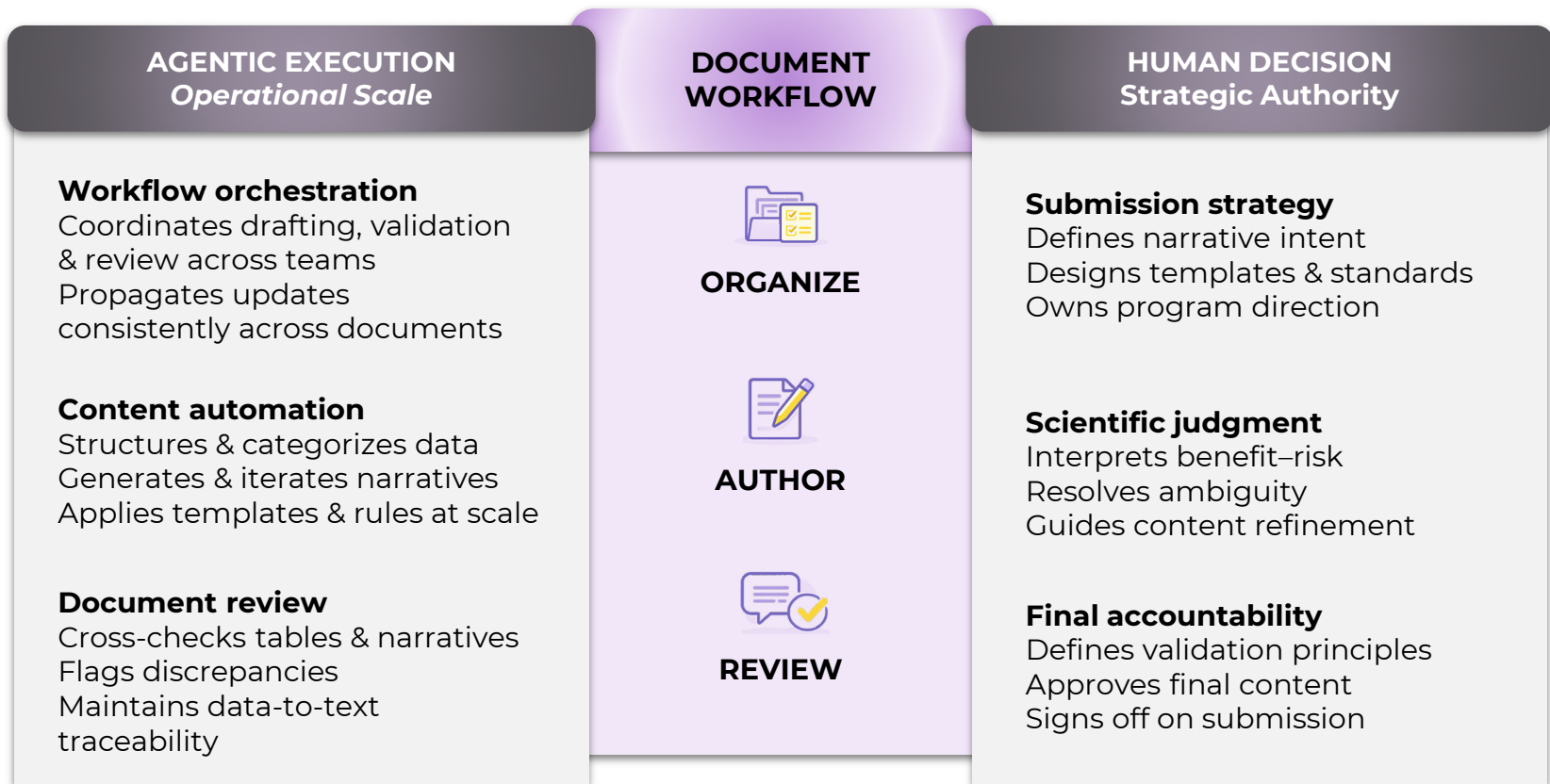
Knowledge Database

Lesson 2

Scaling requires workflow-integrated AI

- Embedded AI within workflows
- Orchestrated drafting, validation & review
- Built in human oversight

AI executes. Humans decide.



Lesson 3

Execution is the bottleneck



Maximize efficiency gains

Governance



Create a Center of Excellence
for templates & training



Clarify authoring &
review workflows



Shift drafting
earlier

Change management



Build a Champion
user network



Roll-out in
phases



Track value
early

Content strategy



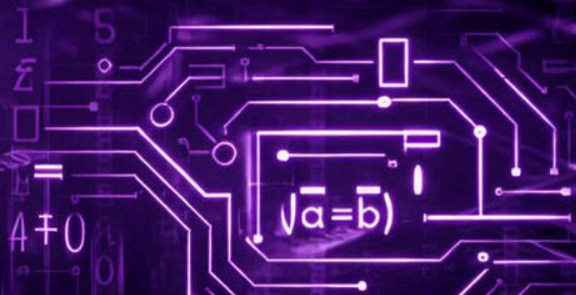
Harmonize
templates



Create consistent
style guides



Map content across
documents



Join the AI revolution
and unlock 90% efficiency gains

Q & A



Thank you!

Stop by **Booth G12** with any questions

*Contact us:
marketing@yseop.com*