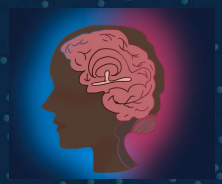
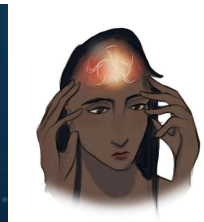




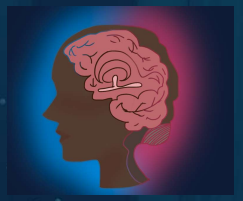
How can the industry navigate regulatory operations for medical devices and combination products using artificial intelligence?

Tanima Ghosh

CAPRA 2025
Medical Device and Combination Product SYMPOSIUM
Dec 3, 2025
Toronto, Canada

QMB
Quality Means Business

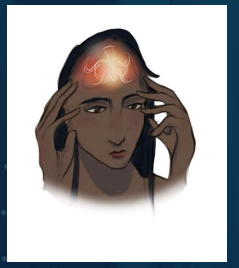
LEARNING OBJECTIVES



- Real-world use cases
- Explain Technology Readiness Levels
- How to simplify the proof of concept phase using AI
- How to navigate from Pre-development, NPD development to NPI using AI
- Learn steps to navigate, build, and productize innovations
- Discuss tactical and strategic tasks to simplify clearance/approval phase
- Transition to the product launch phase to post market surveillance & upgrades.

With the use of AI, we will learn how to build stronger technology roadmaps and compliant technical files with regulatory intelligence so that timelines to navigate from conceptual design to design transfer to full manufacturing production release can be predictable & GTM timelines can be drastically reduced.

Process Transformation



AI is not replacing our regulatory specialists: we are the smartest agile people evaluating multiple datasets in our organizations every week!

A WEEK IN THE LIFE of a Regulatory specialist

AS A [ROLE] ->

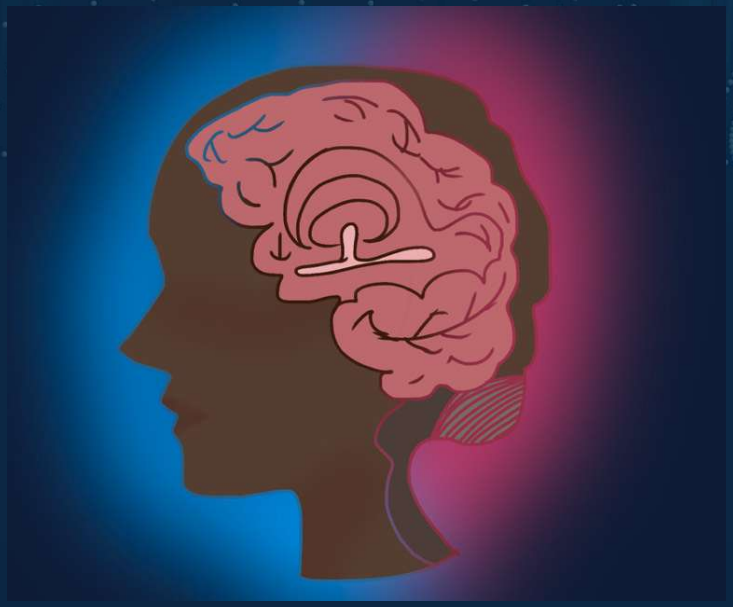
I NEED TO PERFORM [TACTICAL TASKS] ->

IN ORDER TO ANALYZE [CONTEXT]->

TO DECIDE [STRATEGIC REASONING]->

TO CREATE [OUTPUT FORMAT]->

TO DELIVER [STOPPING CONDITION].



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Use cases

USE CASE #1: AI algorithms can be used within medical devices

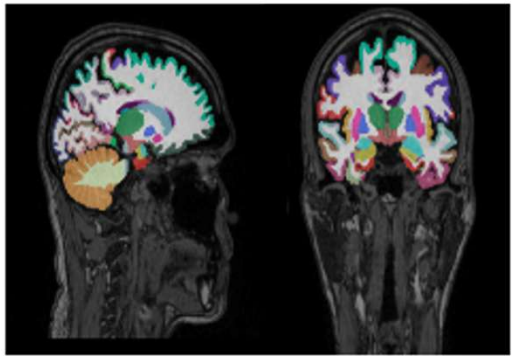
USE CASE # 2: AI can be used to help develop medical devices.

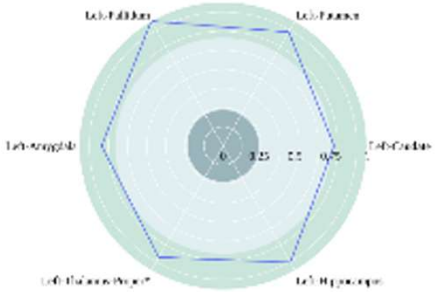
Use case #1: Use AI in SaMD

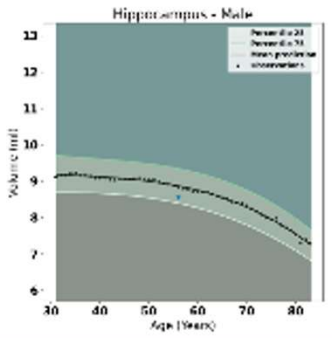
Brain Analytics

- Brain volume (63 ROIs)
- ICV
- Brain age estimation
- Comparing to normatives

ROI Name	ROI volume	ROI percentile plot
brain_volume	1147.4	
ventricle	17.926	
Hippocampus	8.559	
Temporal_lobe	219.46	
Frontal_lobe	423.65	
Parietal_lobe	220.79	
Occipital_lobe	100.66	







Use case #1: Use AI in QIH SaMD

Sample Regulatory Strategy - BRAIN STRUCTURES/WHITE MATTER/ LABELLING/VOLUMETRIC QUANTIFICATION, SEGMENTABLE

Regulation: 892.2050

Class: II

Code: QIH or LLZ

DHF Readiness: 80%
RMF Readiness: 70%
MVP: POC 90%
Formative: 60%
VALIDATION: 50%
Consensus Guidelines: 75%

Intended Use/complexity:

- ❑ X Measurement
- ❑ Normative
- ❑ X Segmentation
- ❑ Detection
- ❑ Diagnosis
- ❑ Lesions suspicious for cancer
- ❑ Identify, mark, highlight Breast lesions
- ❑ Identify, mark, highlight Lung Nodules
- ❑ Lesions detected with ML algorithms
- ❑ Scoring
- ❑ Triage and notification aid
- ❑ ML Prioritization based on specificity/sensitivity
- ❑ Automated image processing non-adaptive ML
- ❑ AI with adaptive ML algorithms

Exemptions:

- ❑ Image Storage
- ❑ Image Communications
- ❑ Non-device Medical Device Data System
- ❑ Non-device Clinical Decision Support System
- ❑ Image Digitizer
- ❑ Image hardcopy device
- ❑ Humanitarian device exemption

Candidate Predicates/References: Class II

AI-Rad Companion Brain MR SIEMENS
510(k)#: K232305, Code: QIH, K232305.pdf (fda.gov)

NeuroQuant: 510(k) : K170981, code LLZ, K170981.pdf

ICOBRAIN: 510(K): K192130, LLZ, K192130.pdf

Quantib Brain plug-in, 510(k)#: K173939, LLZ, K173939.pdf

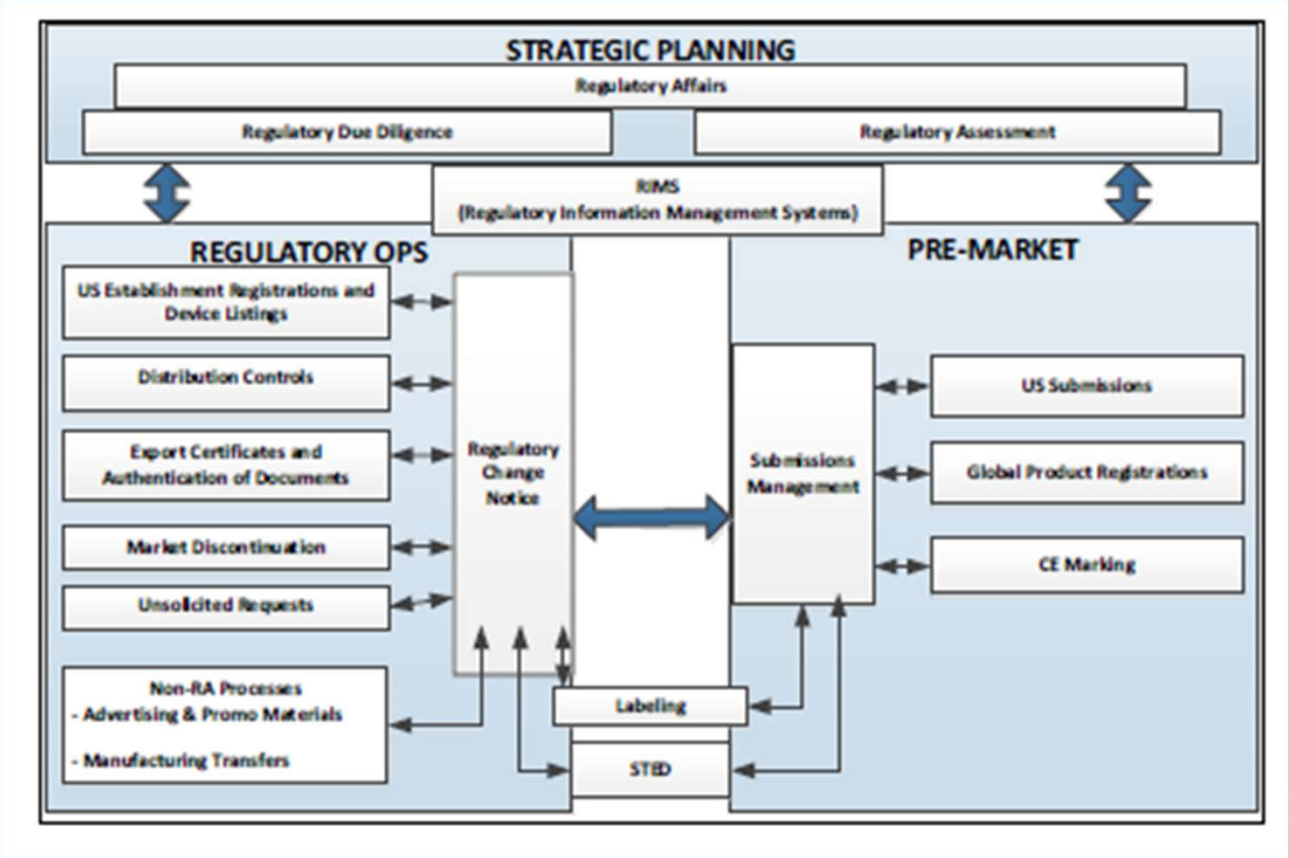
Quantib ND, 510(k)#: K213737, LLZ, K213737.pdf

QP-Brain, 510k#232231 LLZ, K232231.pdf

Regulatory Pathway:

- ❑ X PRESUBMISSION /QSUB PACKAGE
- ❑ X 510(K) : TRADITIONAL, SPECIAL, ABBREVIATED
- ❑ PMA
- ❑ DE Novo
- ❑ Pre-determined Change Control Plan (PCCP)
- ❑ Breakthrough Device
- ❑ Safer Technologies Program (STeP)
- ❑ Clinical trial /Feasiblity studies/IRB
- ❑ Health Canada / MDSAP
- ❑ TGA Australia / MDSAP
- ❑ UKCA / MHRA
- ❑ Singapore / HSA/ MDSAP
- ❑ Letter to File

Use case #2: AI for modernization of Regulatory Submission Management



Streamline tactical tasks for more strategic planning time

expand to Target Countries: USA, Canada, AUS, UK, EUROPE, ROW

Customize regulatory plan for Country readiness

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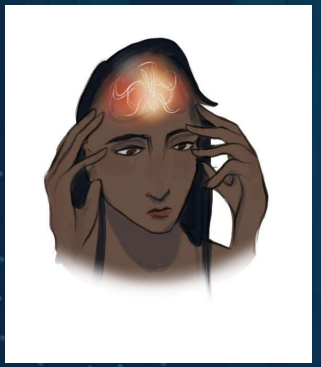
The debate



For either use case, RAQACL teams continue to use TRUSTED MANUAL templates and debate if we should explore AI… while the rest of the industry quietly sprints ahead.

AI systems should be HUMAN-CENTRIC -> SME human in the loop

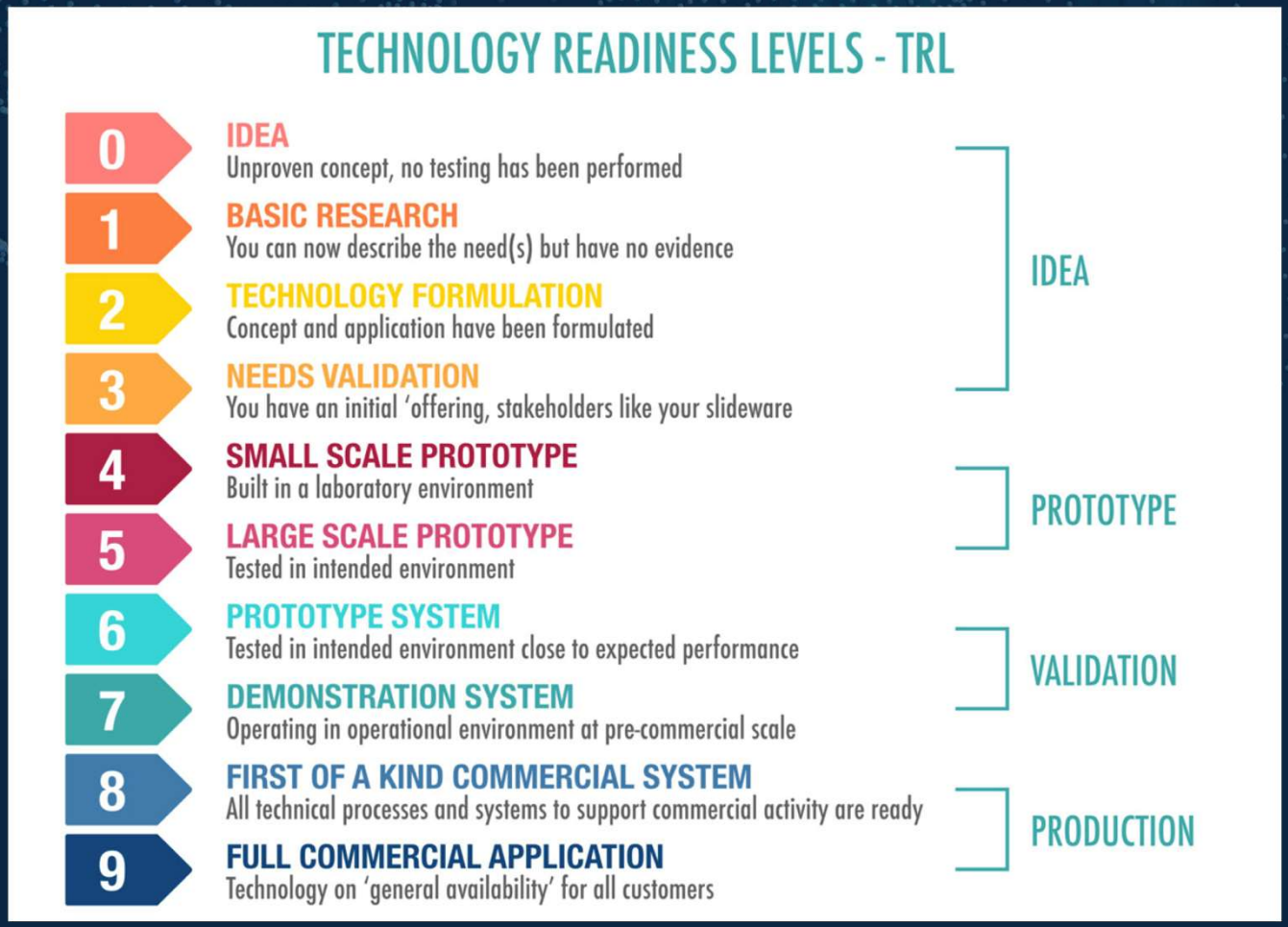
Decisions made by AI should be EXPLAINABLE, TRANSPARENT & FAIR

The challenge:
Alignment of Regulatory Operations with accurate AI Intelligence

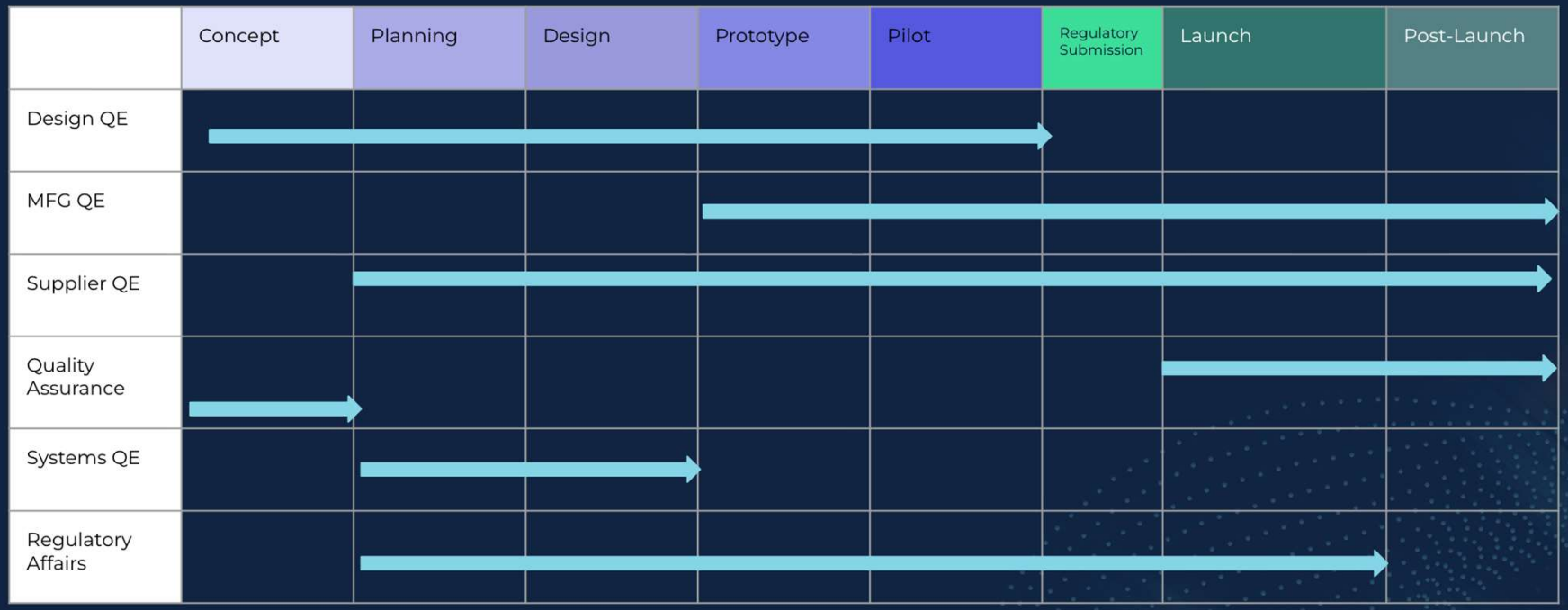
AI is transforming regulatory intelligence by assisting R&D, product and RAQACL teams through critical NPD/NPI steps for multiple products types at different Technology Readiness Levels.

What are TRLs: "Technology readiness levels? "

New product development



AI accelerates progress through stage gates based on AI-assessed TRL levels (0 to 9)



specialist

ROLE-	**As a regulatory specialist, I am both tactical and strategic**
TASK-	**I need to map the workflow, schedule repetitive tasks for multiple products in parallel**
CONTEXT-	**in order to establish the intended use, indications of use and provide the datasets for specified countries and risk classes**
REASONING-	**to justify product code, regulatory plan, substantial equivalence, user needs, SRS, design inputs, design outputs**
OUTPUT FORMAT-	**generate critical project documents in desired format for DHF/RMF/MDF which must comply with the QMS, SOPS, work instructions and forms and submission type**
STOPPING CONDITION-	**pre-submission, clinical study endpoints, clearance, approval, PMS, limited/full manufacturing release**

A WEEK IN THE LIFE of a Regulatory specialist

- Works with R&D & Product teams to define product indications, intended use for all potential products in portfolio

- defines TRL levels for each product in portfolio

- analyzes each product indication, intended use and other parameters to find the right predicates

- navigates each regulation, guidance document & applicable standards

- presents regulatory plans for each jurisdiction including QSUBs, clinical studies at QBR

- executes regulatory pathway , interactive reviews and responses to successfully productize our FDA / Health Canada, TGA, EUMDR and ROW submissions.

PRODUCT NAME	INTENDED USE	TRL LEVEL 0 TO 9	CLASS	QSUB	CLINICAL STUDY	AUDIT READINESS	TARGET GTM DATE	TARGET SUBMISSION DATE
ROLE	PRODUCT	R&D / QE	RA	RA	CL	QA	PRODUCT	RA
PRODUCT A	INFUSION PUMP, CARTRIDGE/ ACCESSORIES SAFETY SW	5	FRN – CLASS II MRZ PHC	MAR5, 2025	COMPLETED	510(k) + PCCP DHF-75%,RMF-75% V&V- 60%, MDF-60% SAC- 75% QMS 100%	USA / CANADA APR 1 2026 AUS Q4 2026	510(K) DEC 31, 2025
PRODUCT B	Detection + diagnosis + Scoring + Triage	3	DE NOVO CLASS III	OCT 26, 2025	PROTOCOL STARTED	DE NOVO- MDF 40% QMS 75%	USA OCT26, 2026	30 DAYS AFTER V&V
PRODUCT C	Quantification brain volume landmarks	0	QIH – CLASS II	FEB14 2026	IRB SELECTED	QSUB PACKAGE- 30%	USA/CANADA Q3-2026	APRIL 19, 2026
PRODUCT D	INFUSION PUMP SOFTWARE PROGRAMMING, DATA ANALYSIS, TRACKING, TRENDING, ERROR REDUCTION, ALARMS	5	PHC	MAR5, 2025	COMPLETED	510(K) + PCCP: 75%	USA APR 1,2026	510(K) DEC 1, 2025
PRODUCT E	INFUSION PUMP	9 USA 5 EU 5 BRZ	EUMDR CLASS III	MAR5, 2026	IN-PROGRESS	EUMDR- NB SELECTED MDSAP – BLOCKED	PORTUGAL/ BRAZIL JULY 1,2026	510(K) DEC31, 2025
PRODUCT N+1	PRODUCT CODE/ NBOG	0 TO 9	CLASS I, II, III, IV	2026	IRB AGREEMENT	DHF/RMF % V&V % QMS%	USA AND ROW	30 DAYS AFTER V&V

How can AI navigate through multiple workspaces and Critical NPD/NPI steps for each product A through E based on TRL?

Critical NPD/NPI decision steps for each Technology Readiness Level

Simplify problem: navigate multiple silos of data

From Product Concept to RA Submission— multiple workflows & workspaces

Upload Product Details

AI determines classification, product code, and regulatory pathway

Risk Detection + Expert in the Loop

Risk flagged via our proprietary 7-point model

Human regulatory experts are available to review and refine.

Documents Drafted

Required documents drafted instantly

Submission-ready package delivered

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MAKING

“Without data, you're just a person with an opinion.”

How can AI provide GOOD DATA to help construct credible steps needed by the cross-functional team to clear / approve our innovative devices and GO TO MARKET FASTER ?

Use AI to navigate NPD/NPI decision steps for each TRL

- to be more agile during the total product lifecycle from concept to NPD
- to navigate through all design/development phases based TRL level
- to pass and transfer through each product stage gate through NPI
- to fasttrack regulatory submissions for each jurisdiction
- to simplify design transfer -> NPI -> physical production
- to generate and maintain audit-ready technical documentation
- to provide credible GTM dates at each Quarterly Business review
- to productize more combination /medical device products.

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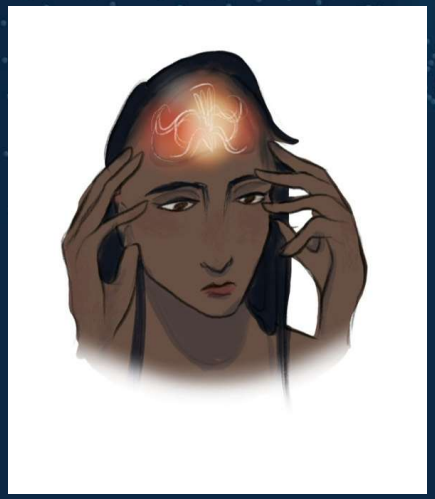
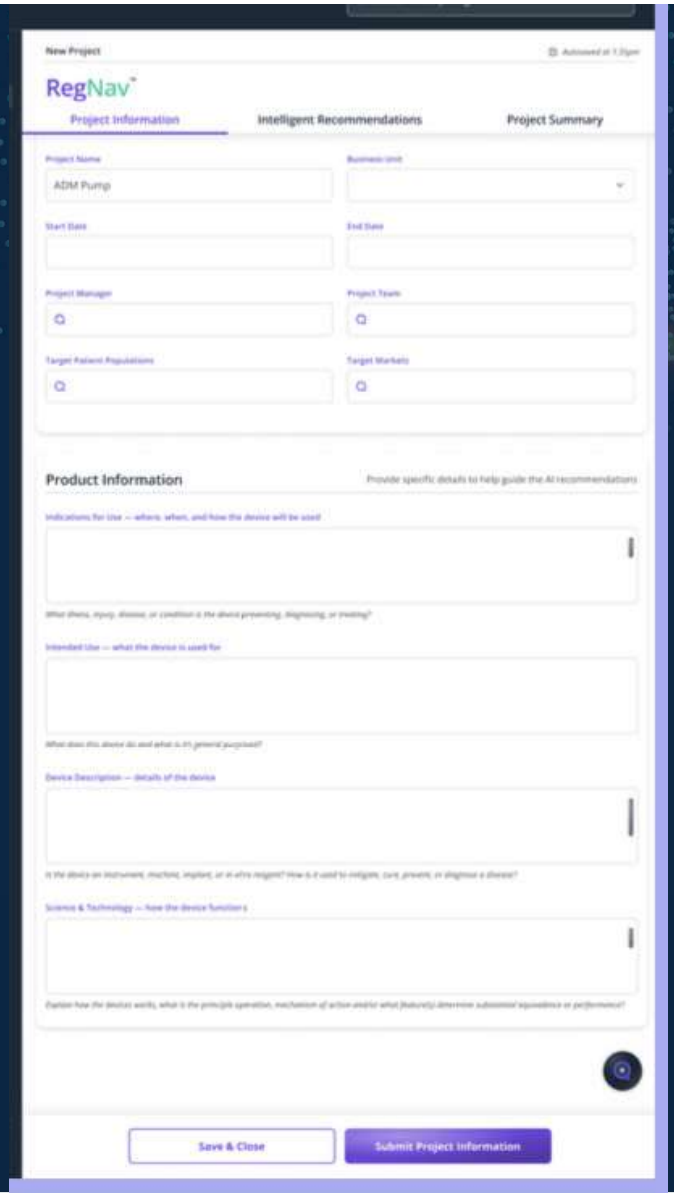
Regulatory Specialist asks the cross-functional team:

What is my intended use?



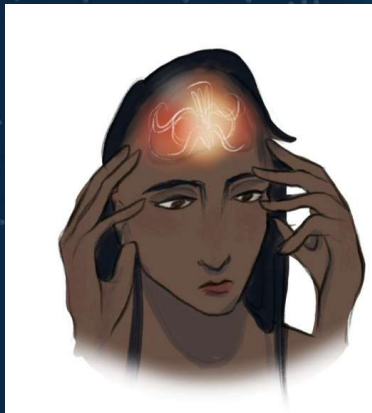


Interview Product Manager, collect AND analyze data using AI for each product A,B,C,D,E:

- TRL level
- patient population
- indications for use
- intended use
- device description
- device functions

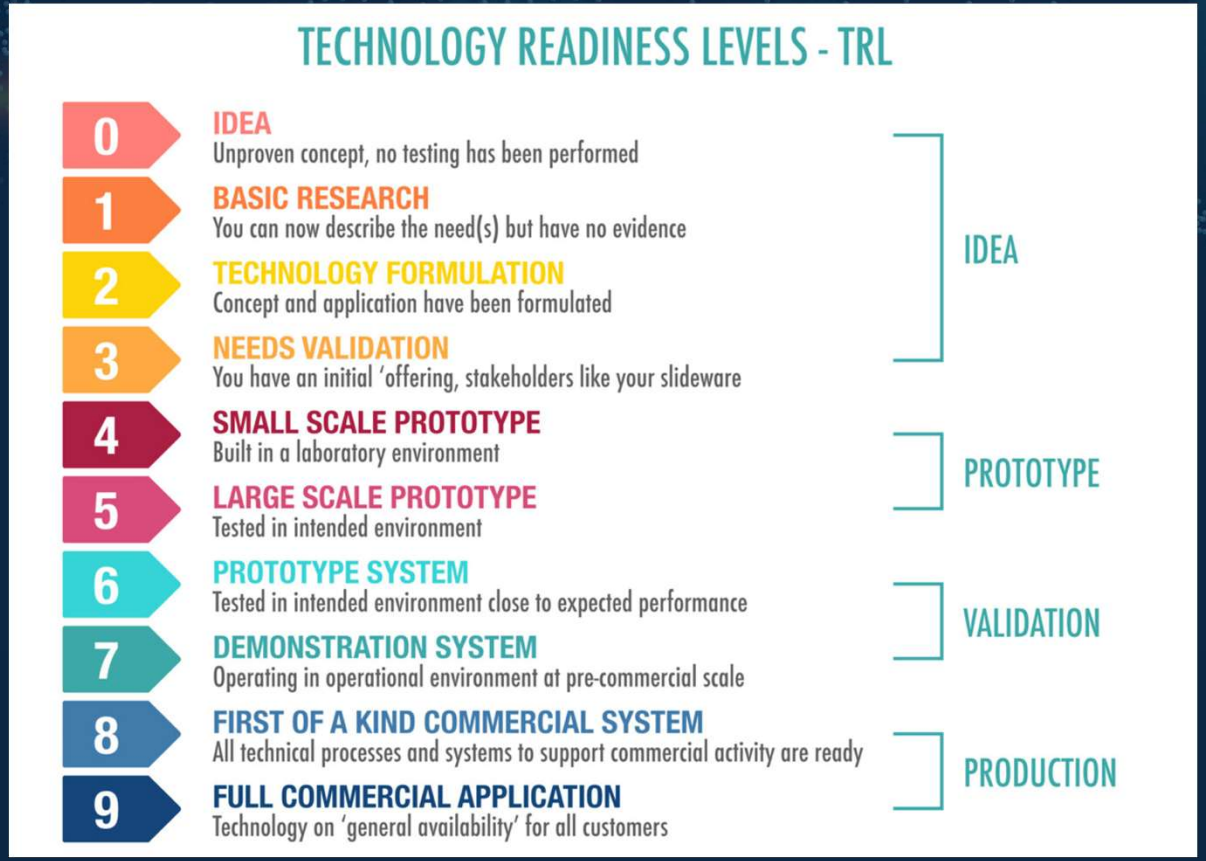
Regulatory Specialist asks:

What are my user needs for productization?

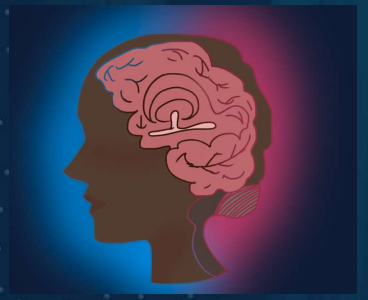


Regulatory Specialist asks:

What is my REGPlan based on TRL readiness?

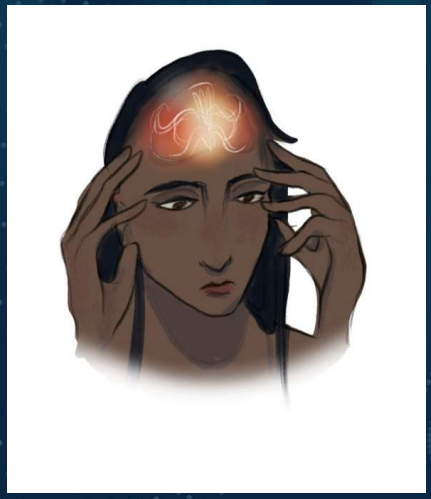


Gate 0 Input:



- is this a medical device?
- is this a new device, improvement or change to existing device?
- key end users (patient, admin, HCP)
- high level hardware/software claims & description
- primary mode of action (device, drug, biologics)
- main component functions (hardware, software)
- equipment block diagram checklist
- data management flow checklist
- do we need clinical data for jurisdiction?
- do we have any critical strategic suppliers?
- combo drug product safety, identity, quality, purity, potency and stability (if applicable)
- IFU /user interface / patient report : languages ?
- existing QMS with SOPs and work-instructions?
- AI/ML enabled functions?
- desired country launch timelines (USA and ROW)
- desired launch date and launch environment

Gate 0 Output:



- preliminary intended use statement
- importer/distributor agreements
- pre- Request for Designation (if needed)
- relevant GMP requirements for the combo product:
  - drug - GMP 21CFR part 210/211,
  - biologics - GMP 21CFR part 600 - 680 ; and/or
  - device GMP 21CFR part 820
- current list of relevant external standards for all components
- applicable country regulations / national CA/ required in-country certifications
-strategic supplier agreements
-in-country authorized reps, PRRC, NOC

-Preliminary substantial equivalence table
-Critical Project Documents
- Regulatory submission strategy /country readiness plan

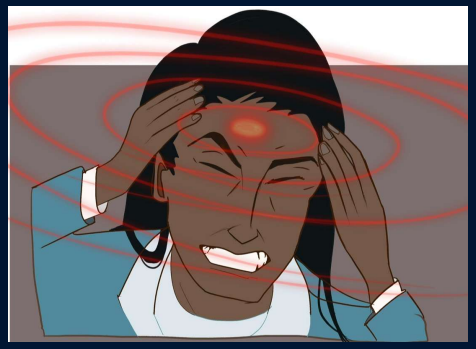
Incomplete DECISION TREES
- Can be the root cause of a warning letter…

Is it a medical device?
What is the intended use?

What is the design development plan?

What is the risk management plan?

What is the Risk Classification?



Is there a predicate device?

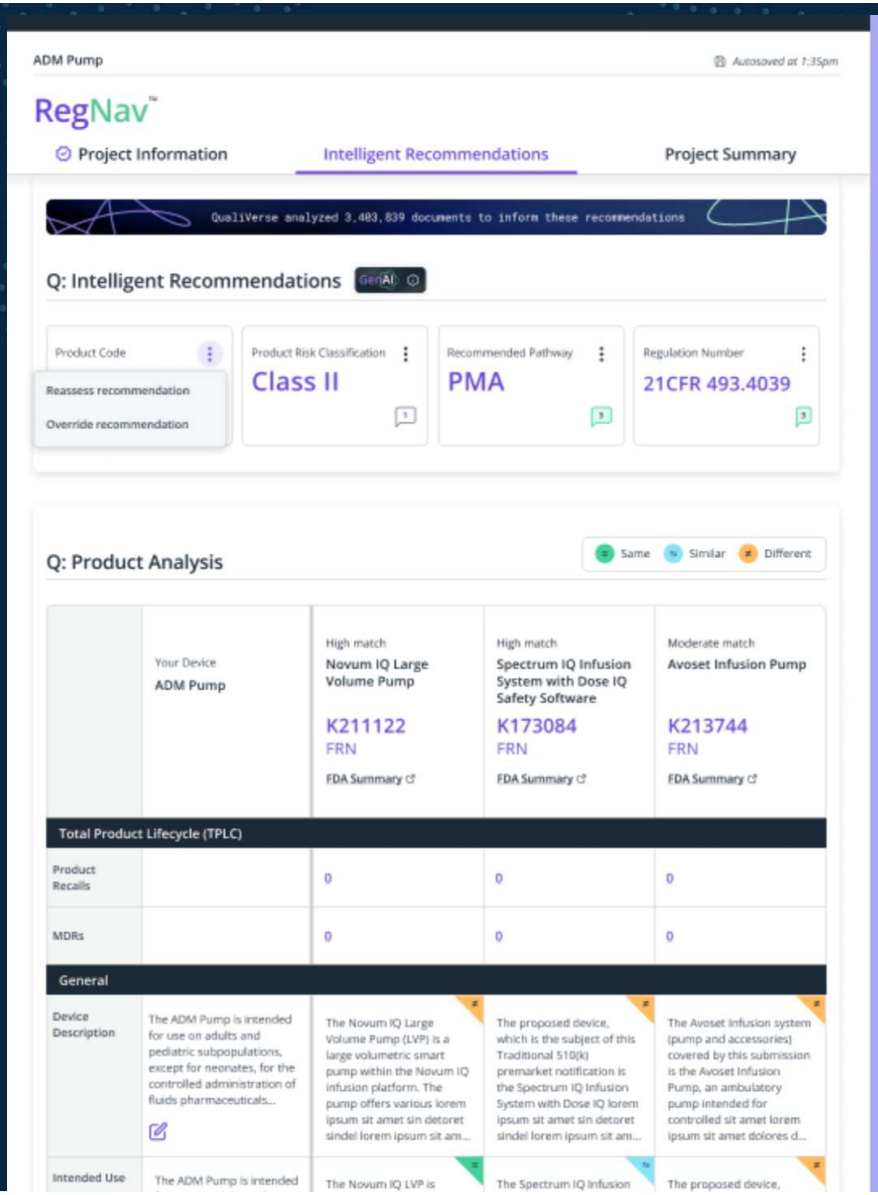
What is the product code

What is the documentation level?

AI navigates DECISION TREES

We use decision trees to:
- establish traditional vs accelerated submission pathways
- Select data from a master picklist,
- Justification of risk classification,
- Documentation level (basic or enhanced),
- Potential predicate device(s),
- Potential reference device,
- Potential product code(s)
- Patent infringement risks

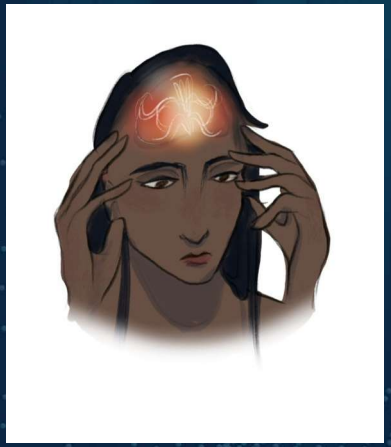
Generate a custom Regulatory plan aligned with design development plan and risk management plan for each subsystem in the equipment breakdown structure.



Use decision trees and research multiple global sources to effectively select the best matches:

- Select candidate predicates
- Justify risk classification
- Evaluate technological characteristics
- Determine regulatory pathway

Good data at Gate 0 helps progress to Gate 7



- AI can help create a KANBAN & preliminary GANTT chart from Design review
- and useability dates of Alpha, Beta and production equivalent releases:

- - intended use, classification, product code (Gate 0)
- - User needs review (Gate 1)
- - Design inputs review (Gate 2a)
- - CMC checklist review (Gate 2b)
- - Formative Evaluation 1 - Alpha release
- - Design Verification review (Gate 3)
- - Formative Evaluation 2 Beta release
- - Design Validation review (Gate 4)
- - Clinical study data review (Gate 5)
- - Design traceability matrix review (Gate6)
- - Summative Evaluation - product equivalent release
- - Design Transfer to Production checklist (Gate 7)

Evidence-based decision making by REDUCING THE MUDA

Muda (無駄) is a Japanese word meaning "futility; uselessness; wastefulness",[1] and is a key concept in lean process thinking, like the Toyota Production System (TPS) as one of the three types of deviation from optimal allocation of resources (the others being *mura* and *muri*).[2] Waste reduction is an effective way to increase profitability.

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NAVIGATING THE MUDA

“MUDA” is a Japanese term in lean management that refers to any activity that consumes resources without adding value to the end customer.

Artificial Intelligence (AI) enhances traditional lean practices reducing the MUDA by providing data-driven insights and automation to identify, predict, and eliminate these wastes more efficiently and at a greater scale than manual methods

THE LIFE of a Regulatory specialist

ROLE-

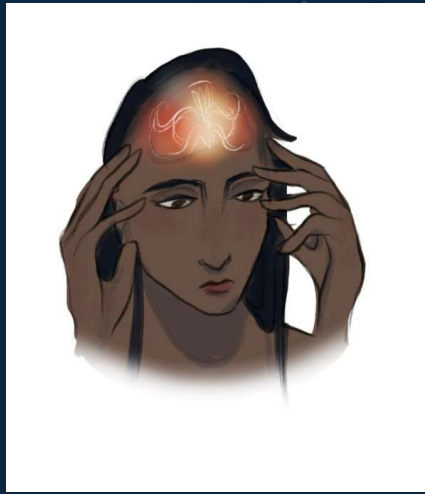
TASK-

CONTEXT-

REASONING-

OUTPUT FORMAT-

STOPPING CONDITION-



Use AI to Analyze Data more efficiently focused on TASKS, CONTEXT & REASONING

- Define Data types

- Ask for Data types from different subgroups

- Collect Data types

- Group into Datasets

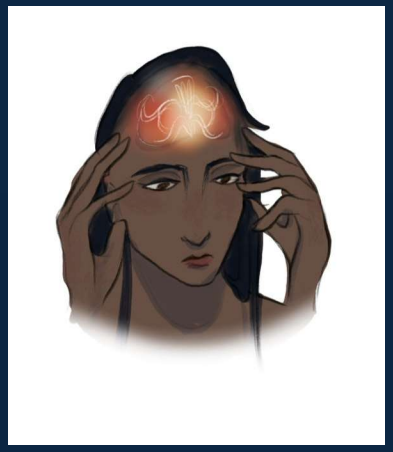
- Clean-up Data sets

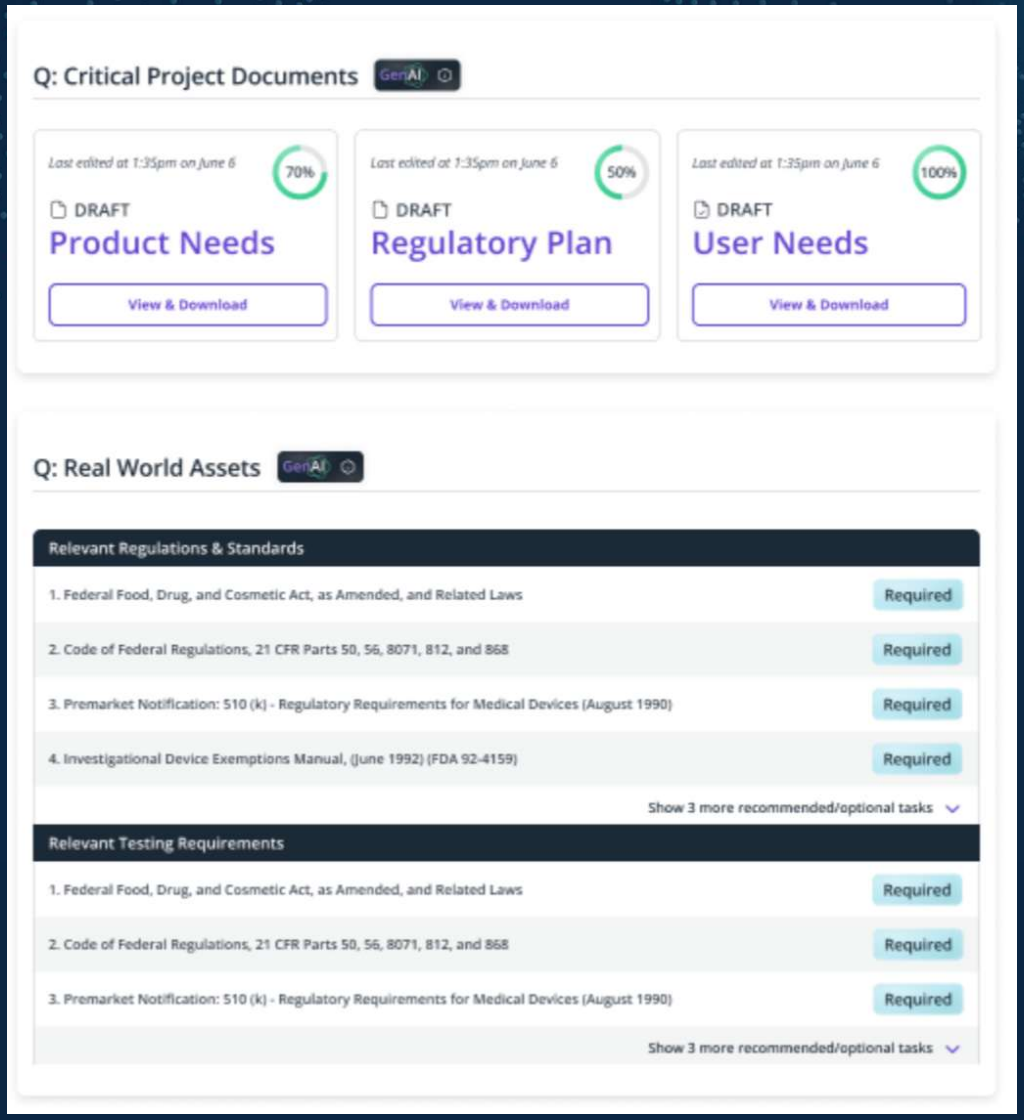
- Enrichment of Datasets

-Data insight extraction

Regulatory Specialist asks:

What is my REGOPS Roadmap?





40 hours to create

1st Drafts

Critical Project Documents:

- Regulatory Plan
- User Needs
- Design Inputs
- Product needs
- List of Regulations and Standards
- List of testing Requirements

10 x time reduction:

What if a regulatory specialist
can use AI
to help generate
the first draft of all critical project documents

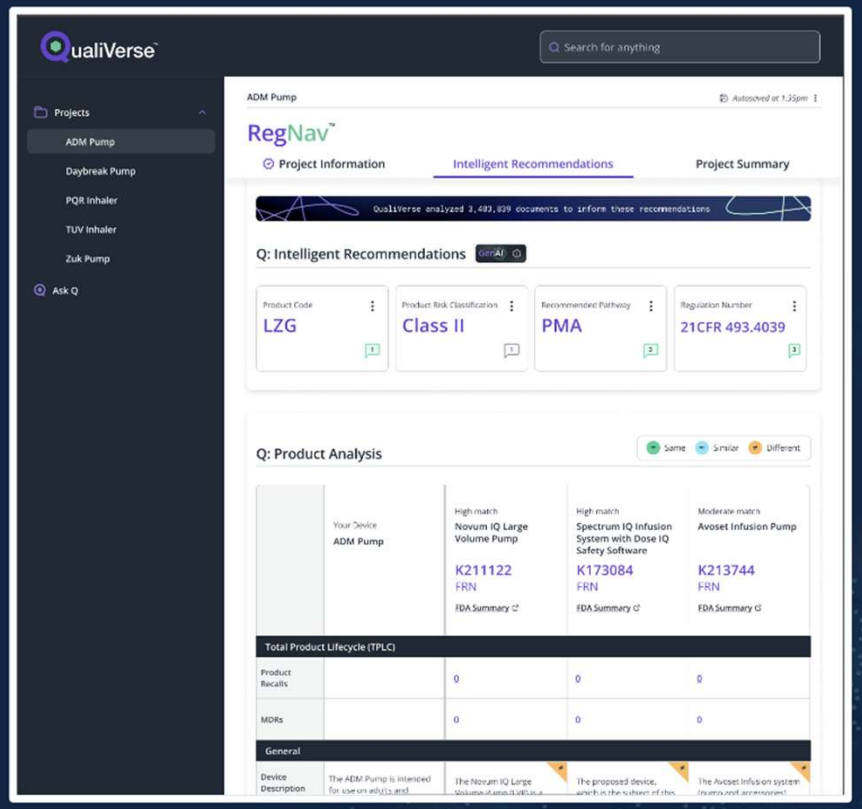
in 4 hrs?

Transformation with AI tools

-automate manual tasks and processes
-Help refine intended use & assess Technology readiness levels
-multiple tactical integrated workspaces for different product codes
-flag and predict risks early for NPD and NPI based on TRL
-predicted risks & milestones -> regulatory outcomes in parallel
-communicate predicted risks and dates to SLT
-manage cross-functional datasets
-continuously assess Audit readiness levels
-assist in strategic decision-making for go-to-market launch and PMS
-productize and launch more combination /medical device products.

AI can help RA improve:

Automating routine tasks & processes



AI can help predict :

What is my "Audit readiness" / Quality Scorecard/ Compliance Score?

AI can provide intelligent recommendations :

What is the State of MDF/ State of the QMS/ Risk of Warning letter?

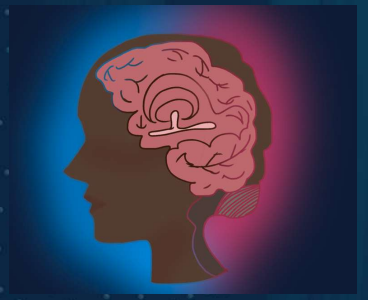
AI can help the Regulatory Specialist strategize:

What is my REGPlan based on audit readiness?

AI can help RA improve:

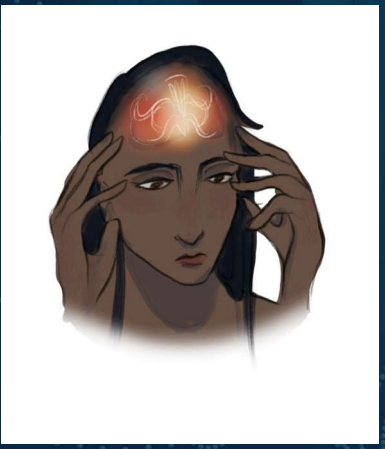
Predicting insights
and
regulatory outcomes

AI can help RA improve:

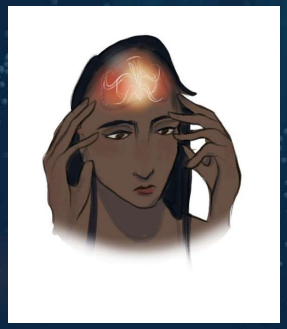


Navigating
and
handling datasets

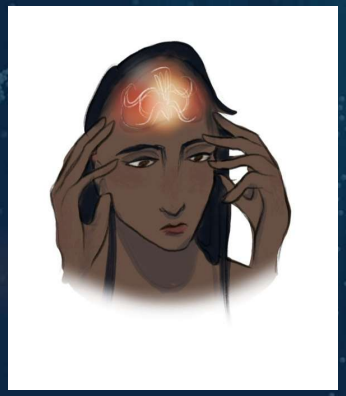
AI can support RA to improve:



How can we better support regulatory and GTM decision-making with credible dates?



AI has already transformed the regulatory specialist role by augmenting human expertise and freeing up specialists from low level repetitive tasks to high value strategic decision making



RE-Focus human experience on complex problems -> strategic communication-> critical thinking

AI will not replace RA specialists.

AI augments workspaces and transforms regulatory intelligence by helping RAQACL teams to predict regulatory outcomes, manage data, automate processes and assist in decision-making in order to productize more combination /medical device products.

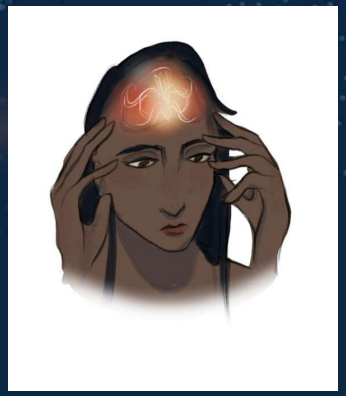
WITHOUT QV	VS	WITH QV
Disconnected Process		Integrated Workflows
Unpredictable Timelines		Predictable Milestones
High Risk		Reduced Risk
Expensive Rework		Accelerated Launch

Transformation through iterative learning

We are lifelong learners.

We are re-discovering how AI can augment and expand our RA toolkits to simplify total product life cycle management by navigating through all phases of a complex combo /medical device product.

Embrace AI- LEAN IN.



Someone else using AI will be a better regulatory specialist – lean in to make yourself even smarter, streamline regulatory submissions, flag risks, predict better dates and deliver expert-validated compliance at scale.

Thank you!

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