



Generative AI for Engineering in the Pharmaceutical Industry

Unlocking the next frontier in value creation by leveraging generative AI's inherent modality creation capabilities.



Generative AI Holds Tremendous Potential Value

ASPIRATION

WHERE TO PLAY

What if we leveraged **generative AI** in the **engineering departments** of pharmaceutical organizations to **generate first-draft documents** across the **project lifecycle & beyond**?

HOW TO WIN

E_v

Economic Value by **reducing** initiation to **first draft creation time** for 20 – 100 documents yearly per engineer by up to **80%**

+

E_x

Experience Shift of **highly skilled engineering profiles** to more value-added activities

+

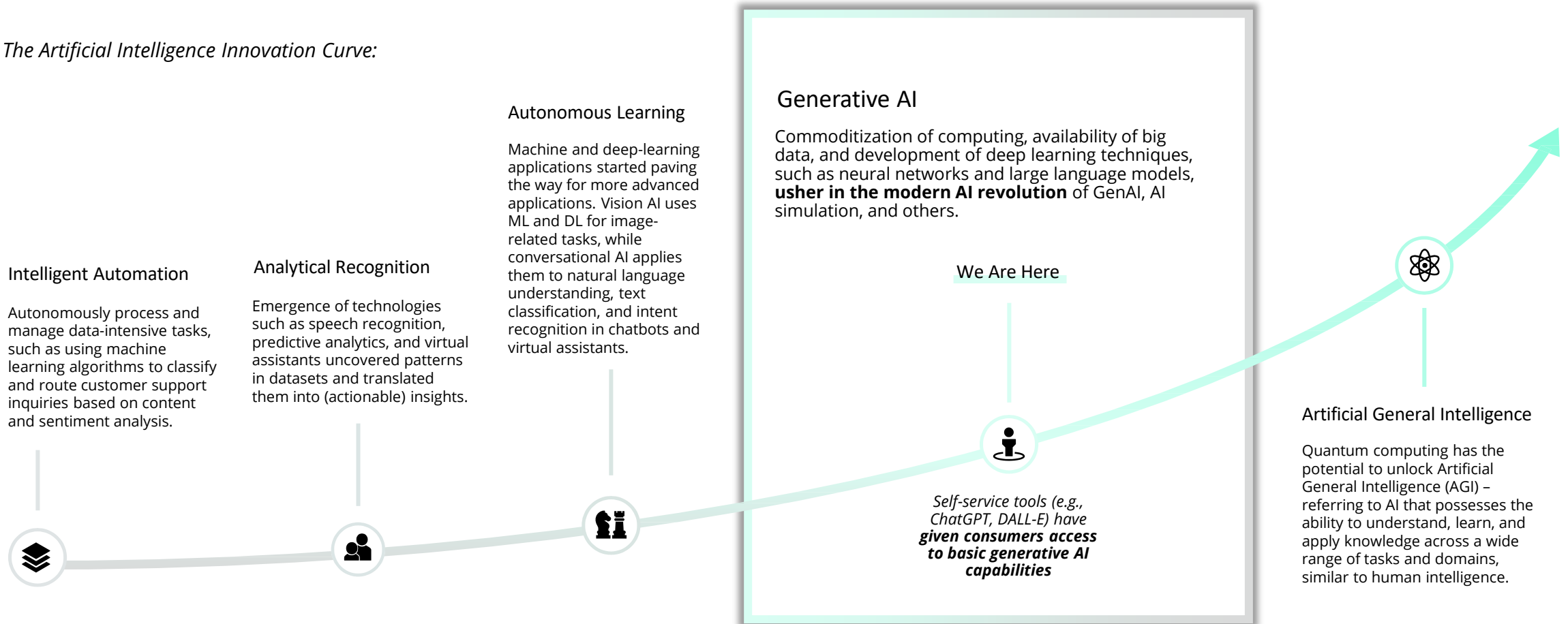
C_A

Competitive Advantage through improved **accuracy, completeness, compliance** with regulations, and document **effectiveness**

Democratization of Generative AI

Generative AI is a form of AI that has recently been democratized by applications such as ChatGPT or DALL-E. This brings with it immense opportunity across industries to apply & resolve issues and bring huge productivity improvement across the board.

The Artificial Intelligence Innovation Curve:



Pharmaceutical Industry Reaction to GenAI

This democratization and subsequent rapid expansion of generative AI has Pharma Players bring strategic focus to building applications leveraging this disruptive technology.

Disclaimer: These are widely recognized examples of initiatives found in public domain. Many are currently underway with much broader scopes and functions than what has been publicly portrayed.

Range of benefits: Considering the use cases we have observed in the industry, it is essential to evaluate each use case individually.



Study Regulatory Submission

Roche is using generative AI to automate data entry, process CSRs, and streamline regulatory submission



Drug Discovery

Amgen is using GenAI to accelerate the drug discovery & development process



Compliance Consultation Automation

AstraZeneca is using a GenAI conversational robot to tackle high volumes of compliance consultations



Protein Engineering Platform

AI Proteins has developed a tool to design new protein structures, and construct and screen libraries to find the best binders



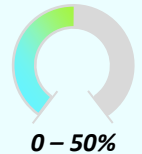
Therapeutic Program Advancement

Sanofi is using Insilico's generative AI suite to nominate preclinical candidates and advance therapeutic programs into human clinical trials



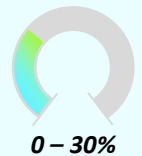
Productivity

Efficiency of the process, typically quantified by assessing the output achieved per unit of input (e.g., hours worked or resources used). It also considers how effectively tasks are completed within the defined timeframe and budget.



Cost

Total expenditure incurred throughout the project, encompassing expenses such as labor, software, equipment, and overhead costs. It helps assess the financial efficiency of the project and ensures it aligns with budget constraints. Organizations will unlock possibilities to reduce internal FTE hours and spend towards external contractors.



Quality

Degree to which the generated content meets established criteria and industry standards, evaluating factors like accuracy, completeness, compliance with regulations, and document effectiveness.



¹Generative AI in Life Sciences Market. (2023, June). Retrieved from MarketResearch.biz: <https://marketresearch.biz/report/generative-ai-in-life-sciences-market/>

Life sciences firms are expected to **spend nearly \$1B by 2032** on GenAI¹, with 50% of companies planning to build a robust AI strategy by 2024.

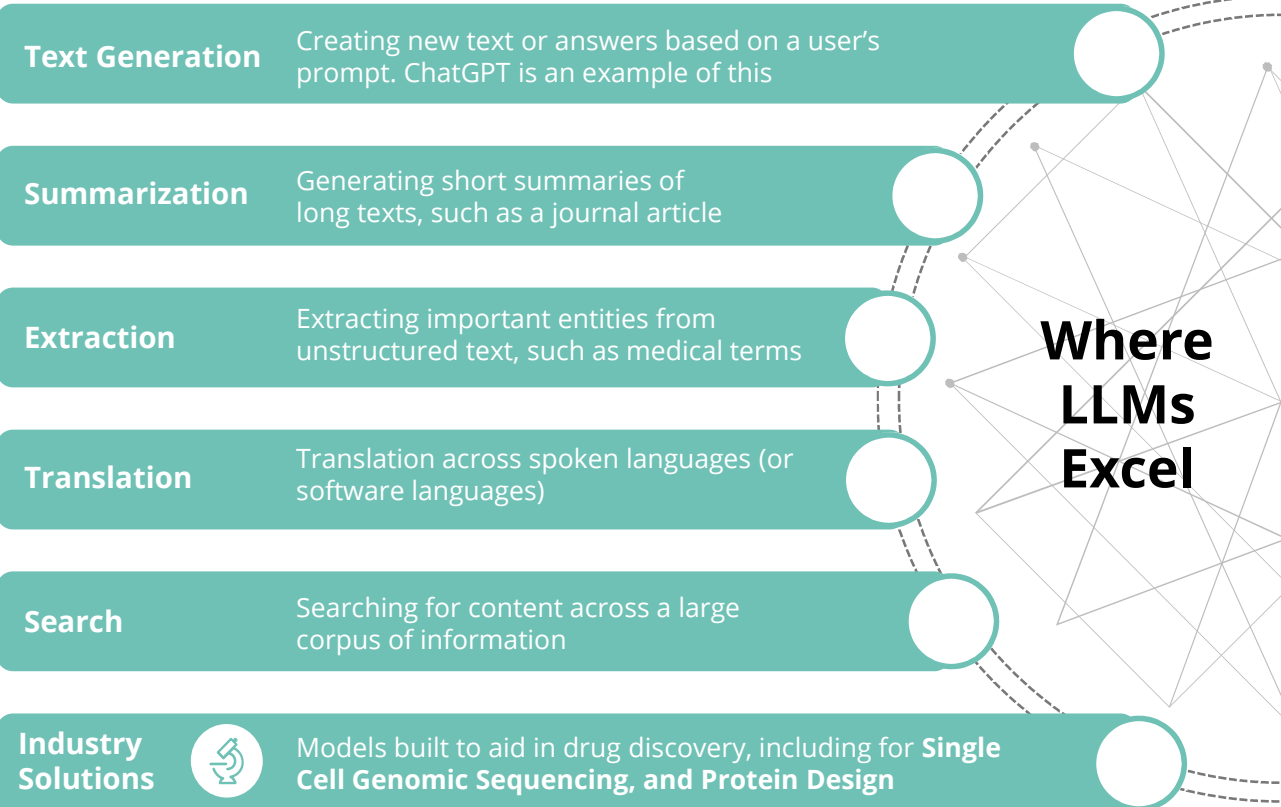
Most Companies are creating a separate fund to **drive business transformation using Gen AI** with CIO leading the charge.

Large Language Models: Core Capabilities

While ChatGPT has garnered attention lately, there are multiple types of Large Language Models – each with its distinct capabilities that can be applied across a range use cases.

What are Large Language Models?

“ A subset of **Generative AI** solutions trained on billions of pages of content directed towards completing a specific task, most often for natural language use cases ”



What this means for Engineering

Based on discussions with engineering stakeholders across the pharmaceutical industry, recurring pain points came to the surface where generative AI can play a pivotal role. Some illustrative points.



Emma is a **global engineer** and part of the organization's **business excellence team**. In her role, she leads:

- › **Project management** and **reporting** for programs and initiatives from feasibility study to commissioning & qualification, and handover
- › **Documentation** and **knowledge** management scattered across network



Alex is a **global engineer** and part of the **capital program team**. For large programs, Alex focuses on a broad range of activities:

- › Creation of **purchase orders** to request external engineering company services
- › Writing **technical contract insurance** policies for collaboration projects with external engineering companies



George is part of the **local site engineering team**. On a day-to-day basis, George is involved with amongst others:

- › Creation of **local technical documents** (e.g. design standards) and procedures based on global guidelines
- › **Compliance verification** of local procedures versus new global guidelines

PAIN POINTS ACROSS THE BOARD

NON-EXHAUSTIVE:



Creation of thousands of **similar documents with subtle nuances** based on location, activity, or contracted organization (contextualization)



Repetitiveness of certain activities for the engineering team, with potential to **shift unique skillset** to more value-adding activities



Consistency of created documents, and **compliance with global** (e.g. contractual) **guidelines** where relevant



Lack of means to **identify existing relevant (reference) documents** or challenges in **retrieving** these in extensive document databases

Disruptive Value Creation Opportunities

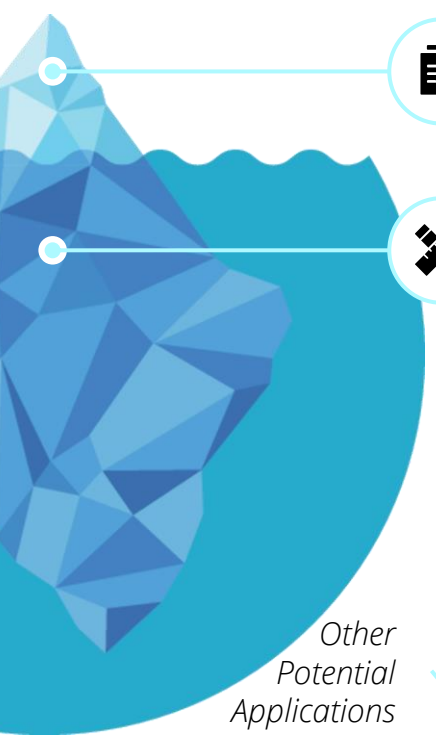
With ample opportunity to apply generative AI across the overall project lifecycle – and beyond – in engineering projects, most organizations have only scratched the surface in how they apply this technology.



Across the board, employees are already leveraging generative AI for some of its most basic applications, such as drafting routine emails, rewriting paragraphs in contracts, or simple idea generation.



Engineering projects follow a structured sequence of phases, from initial conception to final completion. We see use cases with potential value across the overall project lifecycle, and in the collaboration with third party engineering companies to exploit the inherent GenAI capabilities.



Other Potential Applications (Not exhaustive)

1

Feasibility Study

- › **Feasibility study report:** cost estimates, market research, and risk assessments
- › **Business case:** retrieval, structuring, and calculation of key financial information

2

Concept Design

- › **Project proposals:** detailed scope, objectives, initial budget estimations, search & retrieval of relevant reference documents
- › **Risk assessment:** identify and assess project risks, and mitigation strategies
- › **Conceptual design report:** high-level design concepts, preliminary project plans

3

Detailed Design

- › **Safety manuals:** outline safety procedures, hazard assessments, and emergency response plans, tailored to local procedures
- › **QC & QA plans:** outline inspection and testing procedures and detail processes to verify design compliance

4

Construction

- › **Construction phase plans:** detailing health and safety risks and mitigation strategies during construction
- › **Work & specialized permits:** permit application submission preparation (including project plans and details), according to local permitting process
- › **Equipment Testing (FAT & SAT):** test logs, defect reports, summary report sign-off document, user documentation

5

Commissioning & Qualification

- › **Equipment specifications:** detailed equipment specifications based on project requirements
- › **Validation protocols & summary reports:** for equipment, processes, and facilities (IQ, OQ, PQ)
- › **Regulatory submission document:** compile and format regulatory submission documents (e.g. FDA, EMA, PMDA)

6

Post-Implementation Review & Handover

- › **Performance metrics & KPI reports:** compile KPIs and metrics tracked throughout the project
- › **Cost-benefit analysis:** compare actual costs and benefits to initial estimates
- › **Final project report:** compile project data into final report
- › **Lessons learned:** analyze project data and stakeholder feedback
- › **Translation:** to other languages

7

Operation & Maintenance

- › **SOPs:** for manufacturing processes and quality control procedures
- › **Maintenance reports:** equipment status, maintenance activities, parts
- › **Work orders:** includes task descriptions, priority levels, materials required
- › **Failure Mode and Effects Analysis (FMEA) reports:** identify potential failure modes of critical equipment, assess impact and mitigation

Collaborations with external engineering companies across the board: Contract proposal + technical contract insurance

Risks & Limitations

While significant potential value is apparent, generative AI carries risks and limitations as well. This includes the potential for biased or inappropriate content generation, ethical concerns regarding data usage, or IP protection. Human oversight remains at the core to ensure responsible and accurate output.

BUSINESS USE



Although Generative AI is a new innovation, it should be **applied with purpose** and used in concert with traditional AI techniques

- › Avoid using Generative AI just because it is the next shiny object
- › Promote alternative solutions (e.g. traditional AI) where they are more suitable

BIAS



Bias in training data (e.g., over/under-representation of a population cohort, sexism, racism) results in outputs generated also exhibiting bias.

- › Use diverse and representative training data to minimize bias
- › Regularly audit and adjust models to mitigate bias during training and deployment

ETHICAL USE



Generative AI tools may be used in a **manner not intended and to circumvent organizational policies**, laws and regulations e.g., submitting content in competitive events.

- › Ensure that the training data used for generative AI models is inclusive and free from bias to avoid perpetuating stereotypes or discrimination in business applications
- › Implement regular audits for ethical adherence

HALLUCINATION



Models might output results that seemingly look like facts, but are factually false. Sources and citations are unavailable for most models.

- › Incorporate human expertise in the generation and validation process to catch and correct hallucinations
- › Create feedback loops for continuous improvement

IP PROTECTION



SaaS-AI companies may save some or all of prompt information for future training which could lead to leakage of sensitive information including IP.

- › Enforce robust encryption and access controls for data in transit and at rest, ensuring that only authorized personnel can access and handle sensitive information within the software

Continue the Conversation

Reach out to the team below to continue the discussion and see how generative AI can transform your engineering department – and beyond.



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