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APPLICATIONS OF GENERATIVE AI FOR PRODUCT QUALITY AND GxP COMPLIANCE

Generative AI is a type of artificial intelligence that can create new content based on existing content or data. The algorithm is developed by compiling large amounts of data, which serve as the foundation from which the AI model will learn. It functions by utilizing these algorithms to generate outputs that previously would have required human inputs. These outputs may include images, music, text, software, and graphics.

HOW DOES GENERATIVE AI WORK?

A generative AI algorithm analyzes the patterns and relationships within the data to compile the variables controlling its content. The AI model continuously refines its parameters to simulate human-generated content. As the AI generates more content, its outputs become more sophisticated and human-like.

Despite the many potential positive applications for generative AI, there are also downsides and dangers. Generative AI has the potential for spreading misinformation, malicious, biased, or sensitive content. In response to these dangers, in April 2023, the European Union proposed new copyright rules for generative AI that would require companies to disclose any copyrighted material used to develop these tools.

Some examples of these generative AI tools include:

- ChatGPT (the GPT means generative pre-trained transformer) is a free chatbot that can provide an answer to a very wide variety of questions.
- DALL-E (a tool for AI-generated art) is a product designed to use text descriptions to produce images.
- Bard, created by Google, is a chatbox version that features expanded dialogue with users.

GENERATIVE AI, PRODUCT QUALITY, AND GxP COMPLIANCE

Given the widespread applicability of generative AI, the question arises as to whether potential practical applications to product quality and GxP compliance exist. Although not yet a common application for generative AI, product quality and GxP compliance may be able to benefit from its use. Practitioners usually rely on their own experience and expertise to formulate their approaches to the specific situation, such as developing proactive processes or remediating existing ones. Typically, at most, these practitioners may consult with a colleague(s) for additional input and/or to corroborate their own approaches.

The result is that the resolution to any given situation is limited by the expertise of the person(s) doing the work, with possible input from an additional person(s). Perhaps generative AI solutions could be developed that utilize the collective wisdom and experience of many subject matter experts as well as

available historical information. These solutions would then be able to provide a more comprehensive set of options as well as tailored solutions to the situation at hand. Below, we dive into some areas for consideration and examples of how generative AI could be applied.

Example 1: A clinical company is anticipating approval of its first drug and is in the process of expanding from strictly clinical operations into commercial operations. As part of their preparation for the FDA Pre-approval Inspection (PAI), the company is developing their CAPA process. The company has both employees and consultants available with CAPA experience, but optimum CAPA processes vary widely depending on the company particulars. The challenge is developing the optimal CAPA process for the specific company situation as efficiently as possible. Generative AI could be developed with inputs such as:

- company type and size
- product type(s) and number of products
- company organization and position responsibilities
- previous successful or unsuccessful CAPA solutions in similar situations
- applicable regulatory requirements
- previous CAPA-related citations by regulatory authorities for non-compliance to applicable regulations

The algorithm would then generate the process flows and supporting CAPA SOP(s), Work Instruction(s), Form(s), and training materials tailored to the specific requirements of the company for review by the applicable subject matter experts.

Example 2: A medical device company is preparing for a design review of a new device currently in development. A major element of the design review will be a Failure Mode and Effects Analysis (FMEA). The task of identifying all of the potential failure modes and their impacts is challenging because the product is not yet in production, let alone distribution and actual use. Therefore, no data about actual failures yet exists. Generative AI could potentially address this challenge and be developed with inputs such as:

- product type(s) and number and types of its components
- known or suspected modes of failure and associated impacts for the product or product type being developed
- known or suspected modes of failure and associated impacts for similar products and products made with similar materials or technologies (*many of which are likely unknown to those preparing for the FMEA, but exist elsewhere*)
- actual customer complaints and Medical Device Reporting (MDRs) for similar products and products made with similar materials or technologies
- applicable regulatory requirements
- previous design review citations by regulatory authorities for non-compliance to applicable regulations or inadequate responses to known or suspected product failures

The algorithm would then generate a list of potential failure modes, their corresponding impacts, and potential resolutions for review by the FMEA team, who could then optimize the product design to eliminate or minimize the identified failure modes.

Example 3: A pharmaceutical company is formulating its response to an FDA Warning Letter observation that its complaint handling processes are substantially noncompliant. The company has decided that it would be in their best interest to abandon their existing complaint handling processes and completely redesign them. The first challenge is identifying all of the factors that would contribute to developing the most efficient and compliant complaint handling process for their specific situation. The second challenge is developing and implementing the optimum process. Generative AI could potentially address these challenges and be developed with inputs such as:

- product type(s) and number of products
- types and severity of actual previous and potential future complaints
- size of company and organizational structure relevant to complaint handling, investigations, trending and reporting
- previous successful or unsuccessful complaint management solutions in similar situations
- previous successful or unsuccessful resolutions / corrective action to applicable complaint types
- applicable regulatory requirements
- previous complaint management citations by regulatory authorities for non-compliance to applicable regulations or inadequate company responses to complaint management citations

The algorithm would then generate the process flows and supporting complaint management SOP(s), Work Instruction(s), Form(s), and training materials tailored to the specific requirements of the company for review by the applicable subject matter experts and then also provide suggested resolutions to specific complaint types.

INTEGRATING GENERATIVE AI WITH EXISTING TECHNOLOGIES

Generative AI applications could also potentially be used in conjunction with existing technologies supporting product quality and GxP compliance. The intent would be to improve efficiencies and effectiveness in areas where less sophisticated and/or comprehensive levels of technology are already in use. Some of these examples include:

- *Statistical process control (SPC) and other trending*: Generative AI could potentially be used to augment standard techniques by adding real world process adjustments to be made to correct specific statistically out of control situations. Where possible, appropriate process parameter adjustments would then be made automatically.
- *Proactive product defect identification*: Generative AI could potentially be used to augment standard technologies and techniques in use to detect product defects.

- Statistical-based sampling plans have long been in use to identify the presence of product defects. These are constrained by the realities of defects being missed in the actual sample taken, labor intensity of sample testing and inspection, product loss due to destructive testing, and the fact that defect detection is by nature reactive, not proactive. By the time the defect is detected, others may have been produced. The additional defective product then needs to be identified and reworked or destroyed.
- Automated vision systems are used in some applications to detect product defects, such as pinholes in packaging materials for sterile products, and glass defects in vials. As with the previous example, defect detection is reactive, not proactive. Upon defect detection, action needs to be taken, which usually results in some sort of disruption to the process.

POTENTIAL APPLICATIONS OF GENERATIVE AI TO PRODUCT QUALITY AND GxP COMPLIANCE

The potential applications of generative AI to product quality and enhanced GxP compliance appear vast. Subject matter experts in relevant niches could likely envision multiple applications for the technology. The overall challenge is identifying those areas that would maximize, or even justify, the return on investment, considering time, money, risk, and opportunity costs. Some questions you should be asking include:

- *What are the expected benefits of the generative AI application, and can they be quantified?*
- *What are the risks of proceeding or not proceeding with the generative AI application?*
- *What resources would be required to generate effective generative AI for a given application?*
- *How complex, difficult, and time-consuming would implementation of the generative AI be?*
- *What is the estimated value that could be realized if the resources (funds and/or personnel) were to be deployed elsewhere?*
- *How do we ensure the security of the generative AI application and prevent violations of intellectual property rights?*

Simply answering these questions requires resources to be invested in advance of a decision whether to proceed, followed by resources needed to develop and implement the solution, assuming that the project meets the justification criteria.

THE FUTURE OF GENERATIVE AI AND COMPLIANCE

As is the case with the effective adoption of nearly any new technology, detailed analyses need to be performed to determine the suitability of generative AI to the specific application. Given the reality of busy schedules and competing priorities, it's easy to postpone or ignore investigating application possibilities. Doing so may result in missed opportunities for significant benefits and losses due to competitors capitalizing on the opportunity.

Generative AI should be viewed as a useful tool to be leveraged strategically by those in product quality and GxP compliance, particularly in an increasingly digital, complex, and evolving landscape. Best practices as to how it's developed and deployed in the areas of product quality and GxP compliance are far from fully established. Generative AI is expanding rapidly into the life sciences, and it's important to understand its implications and how it can be best integrated into your specific situation. Our team of consultants has the expertise and experience to assist you with navigating the future of generative AI in product quality and GxP compliance.

ABOUT CLARKSTON CONSULTING

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