# The Application of Deep Learning in Quality Assurance for U.S. Pharmaceutical Manufacturing

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## 1. Introduction to Deep Learning in Quality Assurance

Deep Learning has recently been utilized in the Artificial Intelligence (AI) for Automation of Process Inspections and Product Quality Control domains. Generally, in this field, prior models of deep learning are exploited to construct individual deep learning models for each production line or product. To build such models, a great deal of data (a few tens of thousands of images) is required. Since each production line needs an inspection system that uses deep learning models, in a recent approach, a transformer on the base model is proposed to mitigate the need for huge data by re-training the model for each new line [1]. When building product quality inspection systems, there are still various issues to be resolved. Most targets of deep learning methods in product inspections are limited to surface defects, but recently internal quality checking methods using Deep Learning are proposed.

Since more than a few companies are currently developing and commercializing systems that utilize Deep Learning, insights regarding commercial solutions and their status are needed. The use of deep learning for various inspections of semi-finished products is also becoming an issue and consideration regarding the applicability of thorough inspections and their algorithm development is required. Process feeding deep learning models as a first step of a multi-sensor decision-making system is also an interesting topic. All of these new challenges require some analyses to seek an appropriate direction. In this perspective paper, recent trends will be reviewed focusing on the application of Deep Learning in the domain of product inspection methodology.

## 2. Challenges in Quality Assurance in U.S. Pharmaceutical Manufacturing

Process control and quality assurance are critical to the pharmaceutical industry. Specific product characteristics including composition, purity and potency are established by regulations, manufacturing is controlled to make the characteristics time-invariant. For this

purpose every unit produced is tested and off-spec products discarded. However, testing is often based on time-consuming laboratory analysis, which slows down production. High dimensional data containing potentially valuable information is often produced but seldom used. Therefore, the pharmaceutical industry is looking for new efficient technologies to improve process control. These improvements could benefit from digital advances [2]. Convolutional Neural Networks (CNN's) -a type of artificial neural network (ANN's)- has shown promising results in quality assurance tasks in other industries. CNN's can exploit multi-dimensional data (e.g. images), are robust to noise and batch-to-batch deviations, and can be prospectively applied, based on historical data. This work investigates the applicability of CNN's for quality assurance in a pharmaceutical production by focusing on two relevant problems: powder uniformity and tablet hardness [3].

Quality assurance has special challenges in the pharmaceutical industry compared to other sectors such as food production or automotive. Like other industries, time-variant quality assurance is allowed up to a certain range of variance. However, for pharmaceutical products there are stringent upper and lower limits on chemical properties set by regulations. This results in a binary classification of off-spec / on-spec character that is especially interesting for CNN's, which have shown high success in binary classifications of tasks in other industries. Also, the consequences for the patient and company in the case of defective units are especially important, as they pose a severe threat to health and could cause the company to go bankrupt, respectively. These consequences call for more sophisticated approaches than time-invariant methods. Quality assurance in the pharmaceutical industry is especially challenging due to high dimensional data containing products from many different unit operations with a wide variety of potential batch-to-batch deviations. Robustness to batch-to-batch deviations is one of the key strengths of Neural Networks in general and CNN's in particular, having shown good results in other industries with studies involving noisy images and images from different production sites, processing plants and periods.

## 3. Overview of Deep Learning Techniques

A deep learning model is a kind of device which can convert inputs to outputs. Despite the various architectures, these devices consist of two principal parts, including (1) weights and biases (parameters), which are real numbers of fixed discrete size, and (2) transfer functions which convert the outputs of a layer into the inputs of the next layer and are nonlinear

functions [2]. Many deep learning models exist in the literature, including recurrent neural networks for time series, convolutional neural networks for images or visual data, transformers for texts, and others. In the pharmaceutical manufacturing domain, some deep learning models have been adopted, like Long Short-Term Memory for historical data interpretation and modeling and Convolutional Neural Networks for imaging and vision tasks [3]. Because the architecture to process data is mostly not known beforehand, models are usually trained on historical data to convert inputs to desirable outputs. Alternatively, non-deep ones try to first model the architecture that processes the data or try to identify correlations and understand the mechanisms between the system components using first principles.

A framework can visualize a single-layer deep learning model. The inputs of a training set are parameters of the data which a deep learning model attempts to rectify, and these include different numeric values. A deep learning model consists of weights and biases, and is a form of non-linear artificial intelligence, which means that each output of the model depends on others, and the interaction is mediated by transfer functions. The goal of the model is to convert the inputs to the outputs, which are pristine results of a phantom or unadulterated state free of any operations or interference as displayed via a first principle model. Before using the model, it is important to separate the inputs or outputs into test and training sets. Training consists of adjusting weights and biases based on back-propagation techniques using measured data (training sets). After training, the model can be applied to unseen data by comparing its outputs with the outputs of the test set (measured data).

## 4. Deep Learning Models for Image Recognition in Pharmaceutical Manufacturing

Domain-specific knowledge and deep learning models were assembled and evaluated for image recognition tasks involving pharmaceutical products, product manufacturing components, and quality assurance processes. Image recognition tasks were developed to identify packaging labels, blister packages, tainted pill tablets, and contamination of blister packs. Deep learning and machine learning models were trained and evaluated on these tasks. Judicious selection of transfer learning models with frozen convolutional layers or few trainable parameters, batch sizes between 32–64, and data augmentation with mixup or flip enhancements generally improved performance on these tasks. Model accuracy and stable inference time performance with minimal initialization cost were important in the application

of model-to-image classification. Improvements in comprehensive product surveillance capabilities and more consistent quality assurance standards were realized, enabling further exploratory electronic commerce opportunities.

U.S. pharmaceutical products were defined to include pills, caplets, lozenges, and soft-gel capsules. U.S. pharmaceutical manufacturing was defined to include product processing, high-throughput product inspection/sampling, packaging operation, and post-packaging quality assurance on production of product packs. U.S. pharmaceutical product processing was defined to include methods for converting raw ingredients and excipients into pharmaceutical products. Product processing components and systems were defined to include components such as fluid bed dryers, reactors, tablet presses, and blister packaging machines and systems for handling powder granulate, fill and seal blister packages, caustic treatments, granulate tablet coating, and pharmaceutical product bottle filling. U.S. high-throughput product inspection/sampling was defined to include sampling of blister packages with appearance, count, and foreign object checks. U.S. pharmaceutical product packaging operation was defined to include filling of bottles with capsules, caplets, or soft-gel, sealing of bottles, and labeling of bottles. U.S. post-packaging quality assurance was defined to include color presence checks, cap-on cap-off checks, label presence checks, and opening and reclosing checks.

## 5. Deep Learning Applications for Defect Detection and Classification

Deep learning is the collection of components and design techniques that support the design, training and use of neural networks that learn representations from data [3]. Convolutional neural architectures work well for such a task, but they require a significant amount of hyperparameter tuning on a per-task basis to obtain good performance [4]. In general, such methods assume that faults are visible, which may not be the case for many manufacturing processes. Automated inspection reduces labor costs and increases inspection capabilities. The detection of defects in images taken with various imaging modalities has a long history. Traditional computer vision techniques have been applied to these problems, such as detecting shapes, color analysis, or texture analysis. In recent years, there has been a shift from using hand-crafted features to employing deep neural networks to learn features directly from data. Approaches based on convolutional neural networks (CNN) have become state-of-the-art in most inspection tasks. CNNs take advantage of the two-dimensional nature of images

and automatically consider translation invariance and locality during the training of the architecture.

These neural networks learn a hierarchy of features of increasing complexity that transform input data into feature representations of lower dimensions, which, in turn, feed into classifiers, e.g., multi-layer perceptrons (MLP). Data augmentation can also be applied to artificial images, such as rotating them or applying filters, increasing the diversity of the training set. The CNN feature extractor improves state-of-the-art classification metrics. Deep learning classifier proposals that do not require a higher-level feature extractor are also seen. In such cases, the CNN is trained directly on the data and is composed of more layers that allow it to learn representations from the raw data. Datasets are usually partitioned into training, validation and test sets to estimate and tune hyperparameters while avoiding over-fitting, which occurs when building models with excessive complexity.

**6. Deep Learning for Predictive Maintenance in Pharmaceutical Manufacturing**

In pharmaceutical manufacturing, many production lines usually have some kind of computer monitoring and control system to assist with maintaining specifications and on-line monitoring of process parameters. However, these systems rely mainly on traditional PID controllers, which cannot recognize abnormal conditions that fall outside normal operation status [3]. Historical data is usually saved for generation, but there is no portable mechanism at hand capable of using this mass of information to extract the knowledge necessary to assist operators. The application of ML techniques may allow for the identification of hidden relationships between input and output variables and strengthen operators' decision-making capabilities.

The smooth operation of a manufacturing process is a requisite to guarantee efficiency, safety, and compliance with production quality specifications. To fulfil this aim, industrial plants find it necessary to undertake the maintenance of machines and equipment. This allows the prevention of unscheduled downtimes that interrupt the manufacturing of products and are likely to be expensive. Over the past decades, a strategy of maintenance relied mainly on a calendar basis and according to the assets standards and manufacturer's recommendations. This approach is not very effective since many scheduled activities may not be needed, but this strategy can be disruptive as well [5]. It does not incorporate the state of the machines and involves high maintenance costs because it usually entails a system breakdown. Thereby,

techniques to make maintenance efforts more efficient by supporting proactive rather than reactive maintenance were researched. Nowadays, the pharmaceutical industry faces increasing complexity in maintaining mass production, which is accompanied by rising costs and regulations.

## 7. Integration of Deep Learning with Traditional Quality Assurance Methods

The focus of this research is on exploring how emerging technologies, specifically deep learning, can be harmonized with existing quality assurance approaches within the U.S. pharmaceutical manufacturing landscape. A synergistic framework can be created where deep learning technologies complement and enhance existing traditional quality assurance approaches. Such an integrated framework allows for the application of latest advancements with in-depth reliability of established quality assurance methods. To evaluate the feasibility of this new framework, two specific use cases are examined where deep learning technologies are integrated with traditional quality assurance methods. For the first use case, safety data from laboratory animal studies submitted for investigative new drug applications (INDs) to U.S. FDA is utilized. Laboratory animal study data submission is a U.S. requirements for new drugs, and consequently, data from these studies are standardized by U.S. FDA. This standardization transforms unstructured animal study reports into normalized safety data based on the FDA Veterinary Medicine Guidance 185 (Guidance). For this use case, exploration of deep learning models is conducted to predict safety issues with FDA approval recommendations in IND submissions using a historical observational dataset constructed from the transformed and normalized records. FDA process reports for IND submissions are also collected as complementary insights. Proposed deep learning models including multi-input CNN-LSTM models examine research questions on how to align with guidance G.6 and findings from FDA process reports on utilizing mechanistic models for new toxicity prediction. Model explainability via attention weights analysis assesses adherence to scientific rigor in safety evaluation to augment semi-automated screening tools for new QC use-case. Consequently, model explainability highlights interpretable feature importance in safety prediction on a drug basis and understanding safety issues with FDA guidance via consideration of study design robust to species effect on toxicity profile of compounds examined [1]. For the second use case, exploratory analysis is pursued integrating leapfrog machine learning models with traditional statistical process control charts in continuous

glucose monitoring studies within the clinical setting supplemented with professionally-acquired laboratory blood glucose level observations.

## 8. Real-World Case Studies in U.S. Pharmaceutical Manufacturing

There is a growing concern surrounding the reliance on costly trial-and-error studies and time-consuming research tools to design new pharmaceuticals. In an effort to tackle this challenge, interest has shifted toward mining existing information to give insightful predictions about unknown drug candidates. Various machine learning (ML) models have been employed to mine datasets from drug discovery and development. Unfortunately, there is often financial pressure on pharmaceutical companies to design drugs of higher efficacy at a lower cost, and these pressures have been acceded to by the incremental addition of new study techniques to the screening cascade. Meanwhile, researchers striving either to repurpose existing drugs or to discover new candidates face daunting problems, in particular when the new target environment is very different from the original [3]. A deep learning approach is offered to tackle these problems.

Deep neural networks (DNNs) are applied to predict the success of pharmaceutical formulations by learning the intricate correlations between the formulation compositions/process parameters and the in vitro characteristics. Two types of pharmaceutical dosage forms (oral sustained-release matrix tablets and oral fast disintegrating films) are chosen as model systems to be constructed using DNNs. After training, the DNNs are able to yield accurate predictions of the in vitro characteristics that are otherwise difficult to achieve through manual design. Moreover, an insight mining method based on DNNs is proposed that enables automatic extraction of the key parameters influencing the formulation performance. Moreover, the data selection and preprocessing method ensures the reliability of the prediction. This effort represents a pioneering step towards the deep learning and insight mining of pharmaceutical formulations, which could assist with computer-automated formulation design and drug discovery.

## 9. Ethical and Regulatory Considerations in the Use of Deep Learning for Quality Assurance

The ethical and regulatory considerations associated with the use of deep learning models for quality assurance in U.S. pharmaceutical manufacturing are critically addressed. Although

deep learning-based model development can be performed without the use of personal information, deep learning models can inadvertently learn confidential and proprietary information [2]. This prompted general recommendations for safeguarding trade secrets when working with deep learning models. Such precautions mainly focus on limiting the number of individuals internally who are privy to the deep learning models and accessing the datasets on which they are trained. Nevertheless, this does not address the risk that would be faced by the industry if deep learning models were commonly shared among the community. Other sectors have taken steps to share and disseminate innovations and models developed after training on proprietary datasets, as was done with the pharmaceutical industry with the "open access model". Such actions would have significant and wide-ranging implications for the pharmaceutical manufacturing industry [6].

On the regulatory side, recent papers discussed how the use of deep learning in different applications within the pharmaceutical industry would have implications for U.S. regulatory bodies such as the FDA. Such papers primarily focus on the implications of general model development, sharing, and dissemination activities. In the pharmaceutical industry, the application of deep learning models for quality assurance is the most likely scenario, as artificial intelligence (AI) has been of interest in quality by design and industry 4.0 concepts. However, quality assurance is also the FDA's role, and as such, it is imperative that this application is addressed to better engage the community in discussions. There is a need to understand how deep learning model development would likely be regulated. There is also a broader philosophical consideration of how best to ensure societal benefit from deep learning model development.

## 10. Future Trends and Innovations in Deep Learning for Pharmaceutical Manufacturing

Recent developments have shown the practicality of deploying deep learning predictive models in quality assurance audits in the pharmaceutical industry [2]. Predictive paradigm approaches that detect redundancy or gaps in standard operation procedures or batch record system inputs benefit from the audit control limits defined in visualizable thresholds. Any deviation from the standardized practice would alert and tag an input as high risk for non-conformance to follow from QA investigators. Besides textual quality audits, parallel planning of deep learning models is ongoing in other QbD-facilitated areas such as process data visualization. Multi-dimensional analyses of high dimensionality and high-frequency

sampling of real-time process data motivate a zone of "difficult to interpret" data as regards holistic understanding. The discovery of patterns or hidden correlations in process variables data based on their hydrodynamic process conditions was targeted by streaming batch process visualizations with dimensionality reduction coupled to clustering tasks. Output supplementing control charts showing a more informative visual on the batch process behavior over time than simple visual time-lapse was behind input predictive indicators. It also provided an insight into a more contextual dimensional understanding of process variables on the occurrence of deviations or non-conforming batches. So far, exploratory investigations of the methodology were focused on modeling process data from biopharmaceutical batch manufacturing with offline post-acquisition analysis, motivating further research towards real-time data streaming networks.

The evolvement of scientific disciplines in research diverse from traditional chemical engineering domains like transport phenomena or linear systems modeling is expressing an appealing trend in employing computer sciences understanding or emerging disciplines to provide complementary innovative avenues to classical areas [3]. AI applications started to emerge in 1956 from explorative pattern observation human behavioral studies. AI was envisaged as a multi-disciplinary research coherence of computer engineering, linguistics, psychology, space engineering, medicine, and anthropology that fostered the broad physic phenomenon of machine learning aiming replicable behavior machine to human responses and communications. Despite high expectations, initial developments under the scope of logic-based programming were not embraced due to disappointing results. Overcoming its nearly 15 years dormant period of AI, in the 1980s, it regained momentum with the development of algorithmic paradigms for neural networks with multiple processing cascades hierarchically that boosted the reproducibility of its concepts in languages like Prolog or LISP.

**11. Conclusion and Key Takeaways**

The U.S. pharmaceutical manufacturing sector is experiencing significant changes due to emerging technologies and innovations such as advanced manufacturing, Artificial Intelligence (AI), and the Internet of Things (IoT). These technological advances, in conjunction with the current global situation of the COVID-19 pandemic, have prompted the FDA (U.S. Food and Drug Administration) to refocus on the ongoing challenges regarding

conventional drug manufacturing operations, and to reiterate the modernization initiatives in Quality Assurance (QA) and Quality Control (QC) systems applied in the pharmaceutical industry [2]. Recently, multiple advanced AI applications have been proposed to investigate the new solutions to the QA/QC aspects of conventional pharmaceutical manufacturing. As one class of AI, deep learning models provide a promising method to investigate data-driven models for automation and advanced modelling of pharmaceutical drug manufacturing processes. This paper contains a review of the recent applications of deep learning-based technology addressing the QA/QC issues in U.S.-based drug manufacturing organizations. The scope of the literature review encompasses deep learning methods that can facilitate the automation and modernization of QA/QC approaches used by pharmaceutical companies in drug manufacturing processes, including formulation, preparation, and processes involving solid dosage forms.

QA/QC data, derived from the data collection, preprocessing, and archiving from QA/QC instruments, are the foundation of the application of advanced modelling and AI capabilities to investigate in-process knowledge for improved performance and long-term stability of pharmaceutical products and manufacturing processes. This is the first literature review focused on the applications of deep learning technology in addressing the QA/QC aspect of pharmaceutical manufacturing in the U.S. market. A causal control variable is the mean value of the measured 'Y' outputs from QA/QC instruments over time, as it is applied to estimate the effect of the change in 'Y' on the observed 'X' inputs. Automated visual inspection characterisation based on CNN techniques applies deep learning structures for on-machine inspection of optical values, overcoming the limitations of conventional machine vision methods.

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