

Intelligent Personalised Training Recommender Systems For Occupational Health Risk Mitigation In Pharmaceutical Industries

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Abstract

Occupational health risks remain acute in pharmaceutical manufacturing, where complex processes and exposure to potent compounds demand targeted safety interventions. Traditional, one-size-fits-all training frameworks often fail to accommodate individual vulnerabilities, role-specific hazards and shifting risk profiles. This study presents an Intelligent Personalised Training Recommender System (IPTRS) that formulates training assignment as a multi-label classification challenge, ingesting operator attributes health status, job function, exposure history and delivering customised module recommendations. We benchmarked three state-of-the-art architectures TabNet, AutoInt and xDeepFM on a real-world pharmaceutical dataset. TabNet achieved a subset accuracy of 85.4 per cent (micro-AUC ≈ 0.998) with near-perfect precision (≈ 0.999) and a recall of 0.922, demonstrating its conservative yet reliable baseline performance. Both AutoInt and xDeepFM attained flawless results (subset accuracy, F1-scores and AUC = 1.0), highlighting their aptitude for modelling complex feature interactions, albeit with a cautionary note on potential overfitting in heterogeneous settings. These outcomes advocate a hybrid deployment strategy leveraging TabNet's high-precision recommendations alongside deep-interaction models for exhaustive coverage underpinned by continuous validation, adaptive thresholding and integration with real-time biosignal and environmental feeds. Practical guidelines for industrial adoption emphasise dynamic content delivery, rare hazard detection and seamless alignment with existing occupational health and safety infrastructures.

Keywords: Personalised recommender system, TabNet, AutoInt, xDeepFM

1. INTRODUCTION

Pharmaceutical manufacturing combines extreme precision with complex workflows and inherent hazards[1]. From the handling of potent active pharmaceutical ingredients under containment to the operation of high-speed tablet presses in sterile environments, even minor deviations can compromise both human safety and product integrity[2]. Despite stringent regulations and continual enhancements to engineering controls, unsafe events persist with human error implicated in an estimated 70–90 per cent of incidents[3]. The economic fallout is equally significant: workplace accidents and ill-health absorb roughly 4–5 per cent of GDP in many economies through lost productivity, medical costs and regulatory non-compliance[4].

Recent advances in artificial intelligence and machine learning have given rise to recommender systems capable of tailoring suggestions to individual users in real time[5]. Within educational and corporate learning contexts, such systems have demonstrated marked improvements in engagement, knowledge retention and performance outcomes. By analysing user profiles, historical interactions and even ambient or physiological data, they can deliver micro-learning modules and refreshers precisely when and where they are needed transforming safety training from a periodic checkbox into a continuous, adaptive process[6], [7].

However, most current training programmes remain “one-size-fits-all”, overlooking the diverse risk exposures and cognitive states of individual operators[8]. Two technicians on the same manufacturing line may encounter fundamentally different hazards one performing aseptic filtration, the other executing equipment calibration. Static, generic modules cannot accommodate such variance, nor can they respond dynamically to real-time indicators of fatigue, workload or environmental shifts[8]–[10]. What is needed is an intelligent personalised training recommender system that continuously harvests selective context ranging from shift schedules and competency records to live biosignals and dynamically curates safety interventions optimised for each user at each moment[11]. Such a system promises to elevate occupational health and safety in pharmaceutical environments by empowering workers with the right information, in the right format, at exactly the right time.

2. Occupational Health Risks and Current Mitigation in Target Industries

This section provides a detailed overview of the specific occupational health risks prevalent in the pharmaceutical industries, along with their respective regulatory frameworks and existing mitigation strategies.

Pharmaceutical Industry: Hazards, Regulations, and Existing Safety Practices

The pharmaceutical manufacturing industry presents a unique set of occupational health hazards due to the nature of its materials and processes. Approximately 24-35 million healthcare workers are potentially exposed to hazardous drugs, highlighting the widespread risk[12].

Overview of Pharmaceutical Industry Hazards:

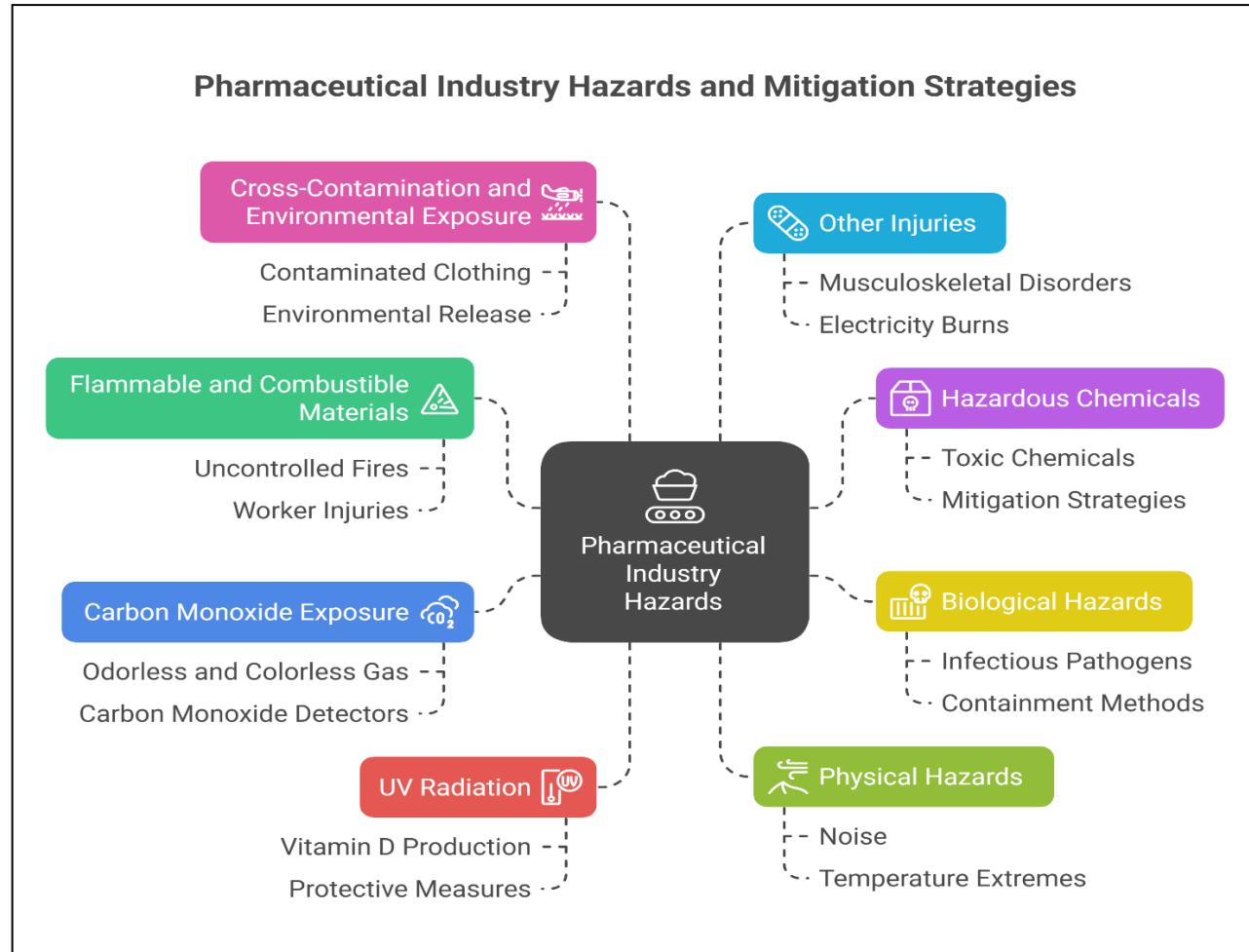


Figure 1 Pharmaceutical industry hazards

- Flammable and Combustible Materials:** These are common within pharmaceutical manufacturing facilities and pose significant risks of uncontrolled fires, extensive property damage, and severe worker injuries, including burns and smoke inhalation[13].
- Hazardous Chemicals:** Working with, handling, transporting, and storing chemicals is a fundamental aspect of pharmaceutical manufacturing. Many chemicals used in both primary and secondary processing can be highly dangerous if accidentally ingested or inhaled. This category includes toxic industrial chemicals, acids, caustic substances, and various forms of chemical hazards such as liquids, gases, vapors, solids, smoke, and fog.² Mitigation strategies include keeping chemicals in their original, properly labeled containers, ensuring appropriate ventilation systems (including biological safety cabinets), and positioning eye-washing and handwashing stations close to work areas[14].
- Biological Hazards:** The pharmaceutical industry frequently engages in experimentation with infectious pathogens, including bacteria, viruses, and fungi, which introduces contamination risks. Solutions involve tightly controlled primary and secondary containment methods, routine handwashing, and advanced ventilation

systems[15].

- **Carbon Monoxide Exposure:** This odorless and colorless gas can develop as a byproduct of certain chemical reactions and is toxic to humans, causing symptoms such as dizziness, weakness, vomiting, and even death upon inhalation. Protecting workers requires the use and regular inspection of carbon monoxide detectors and appropriate signage where the gas is stored or potentially created[16], [17].

Table 1: Key Occupational Hazards and Associated Health Impacts in the Pharmaceutical Industry[18]

Hazard Category	Specific Hazard	Associated Health Impacts/Illnesses	Relevant Mitigation Strategies
Chemical Exposure	Flammable/Combustible Materials	Uncontrolled fires, property damage, burns, smoke inhalation	Proper storage, ventilation, fire safety protocols
Chemical Exposure	Hazardous Chemicals (toxic, acids, caustic)	Ingestion/inhalation toxicity, skin/eye irritation, chemical burns, adverse reproductive outcomes, possibly cancers	Proper labeling, ventilation (biological safety cabinets), eye/handwashing stations, PPE
Biological Hazard	Infectious Pathogens (bacteria, viruses, fungi)	Contamination, various illnesses	Tightly controlled primary/secondary containment, routine handwashing, advanced ventilation
Chemical Exposure	Carbon Monoxide	Dizziness, weakness, vomiting, death	Carbon monoxide detectors, appropriate signage
Radiation Exposure	UV Radiation	Cataracts, skin cancer, burns on eyes/skin	Protective apparel, gloves, eye protection
Physical Hazard	Noise, Temperature Extremes, Humidity	Hearing impairment, heat/cold stress, discomfort	Environmental controls, hearing protection
Cross-Contamination	Contaminated Clothing/Environmental Release	Exposure of families/community/animals to harmful materials	Strict PPE use, decontamination procedures
Ergonomic Hazard	Prolonged Standing/Sitting	Musculoskeletal disorders	Ergonomic workstation design, regular breaks
Physical Hazard	Electricity	Electricity burns	Electrical safety training, proper equipment maintenance

- **UV Radiation:** Ultraviolet (UV) radiation is utilized in various pharmaceutical operations, such as Vitamin D production. Excessive exposure to UV radiation has been linked to an increased risk of cataracts, skin cancer, and burns on the eyes and skin. Protective measures include offering appropriate apparel and accessories to shield eyes and skin from UV light[19].

- **Physical Hazards:** Common physical hazards in pharmaceutical manufacturing environments include noise, temperature extremes (heat stress, cold stress), humidity, and other forms of radiation[20], [21].

- **Cross-Contamination and Environmental Exposure:** There is a risk that workers can unintentionally expose their families, fellow community members, and animals to toxic or harmful materials through contaminated clothing or accidental environmental release[22].

- **Other Injuries:** Less severe but common occupational injuries include musculoskeletal disorders resulting from prolonged standing or sitting, while more severe incidents can include electricity burns[23].

Regulatory Standards and Guidelines:

The Food and Drug Administration (FDA) enforces Current Good Manufacturing Practice (CGMP) Regulations, which establish minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing drug products[24]. These regulations primarily ensure that a product is safe for use and possesses the claimed ingredients and strength. For certain "riskier" drugs, the FDA mandates a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of these drugs outweigh their risks[25]. REMS elements can include

medication guides, communication plans for healthcare providers, and "Elements to Assure Safe Use" (ETASU), such as provider/pharmacy certifications, patient monitoring, and registries. Training and educational materials are often appended to REMS requirements. Additionally, NIOSH publishes a List of Hazardous Drugs in Healthcare Settings, which aids employers in identifying and appropriately handling drugs considered hazardous[26].

It is important to acknowledge a nuanced aspect of risk management in the pharmaceutical industry: the primary focus of extensive regulatory frameworks like CGMP and REMS is often on *product safety and quality for the patient*. While worker safety is addressed, particularly concerning hazardous drugs and PPE, the detailed regulatory emphasis appears to be distinct from occupational health and safety specifically for the *worker*[27].

This suggests a potential difference in the depth of regulatory oversight for product safety versus worker safety, with the latter often falling under broader OHS regulations (e.g., OSHA), which are not as extensively detailed in the FDA-centric materials. This distinction implies that IPTRS designed for pharmaceutical OHS must bridge this gap, not only training on safe handling for product quality but explicitly linking it to *worker exposure mitigation* and *long-term health outcomes*, such as preventing skin rashes, adverse reproductive outcomes, or cancers associated with hazardous drug exposure[26]. Personalization in this context must consider the worker's direct exposure profile, rather than solely the drug's patient risk profile. This necessitates IPTRS that can integrate data from both product-centric quality systems and worker-centric exposure monitoring.

Existing Training Methodologies and Risk Mitigation Strategies:

Robust safety training programs are fundamental for worker safety in pharmaceutical manufacturing[28]. These programs educate employees about proper handling techniques for hazardous substances, emergency response procedures, and the correct use of PPE. Regular training sessions are crucial for keeping workers informed about the latest safety protocols and ensuring preparedness for potential hazards. Personal Protective Equipment (PPE) is an essential barrier against harmful substances, comprising protective apparel (gowns, coveralls), gloves, shoe covers, eye protection (face masks, goggles), and respiratory protection (N95 respirators, Powered Air-Purifying Respirators - PAPR)[29]–[31]. Training on the appropriate use and maintenance of PPE is critical. Process safety is another key area, focusing on preventing fires, explosions, and accidental chemical releases through meticulous facility design, robust control systems, comprehensive hazard identification, thorough risk assessment, and the implementation of proactive safety measures. This includes Safety Instrumented Systems (SIS) for automatic shutdowns and well-developed emergency preparedness plans.

Quality Risk Management (QRM) is a systematic process for identifying, assessing, controlling, and mitigating risks throughout the pharmaceutical lifecycle, encompassing manufacturing, supply chain, and distribution[32]. Key components of QRM include risk identification (often using techniques like Failure Modes and Effects Analysis - FMEA, and Root Cause Analysis - RCA), risk assessment (prioritizing risks using tools like risk matrices), risk control (implementing Corrective and Preventive Actions - CAPA, revising Standard Operating Procedures - SOPs, investing in advanced equipment maintenance, and providing *additional training*), risk communication, and continuous risk review.

A proactive approach is emphasized, focusing on identifying and addressing risks early in the development phase (e.g., clinical trials, manufacturing, supply chain) to prevent later issues. Risk management also requires a cross-functional approach, integrating input from various departments such as R&D, quality assurance, regulatory affairs, and manufacturing to ensure comprehensive mitigation strategies. This framework is often integrated with the company's existing Quality Management Systems (QMS) to align risk mitigation with quality standards.

The industry increasingly utilizes technology and data analytics for risk management. This involves predictive modeling techniques, such as Bayesian methods, to anticipate high-risk areas in drug development[33]. The use of "nontraditional data sources" like online physician communities, consumer-generated media, and aggregated electronic health records (EHRs) for "real-world clinical trials" is gaining traction. This approach supports safety evidence and helps identify rarer events or latent safety issues not apparent in smaller datasets from controlled trials. Industry collaborations, such as the Predictive Safety Testing Consortium, further expand sample sizes and capabilities for safety evaluations[34]. This reliance on diverse, real-world data and inter-organizational collaboration allows for a shift from purely internal, retrospective risk management to a more external, proactive, and predictive approach. Safety signals are often distributed across a wider ecosystem than just one company's internal data, making such broad data integration critical for comprehensive risk identification. For IPTRS in pharma, this means that training content and recommendations should ideally be informed by these broader, real-world safety signals. If a

latent safety issue is identified through aggregated EHR data, the IPTRS could immediately generate or recommend targeted training modules for relevant personnel on new handling protocols or risk awareness, moving beyond static curriculum delivery to dynamic, evidence-based, and continuously updated safety education driven by collective industry knowledge and real-world outcomes[35]. Continuous training and awareness programs ensure that employees at all levels are well-versed in risk management principles, fostering a culture of compliance. Specific online courses cover hazard awareness, PPE use, respiratory protection, ergonomics, and chemical safety, tailored to various roles within the pharmaceutical and healthcare sectors[36]–[38].

3. METHODOLOGY

3.1. Problem Formulation

The task is to assign multiple core safety training modules to employees based on their profiles, treated as a multi-label classification problem. Each employee's profile (a sample) can be associated with multiple training modules (labels), represented as a multi-hot target vector. We binarise these targets using scikit-learn's MultiLabelBinarizer to create a binary indicator matrix Y (samples \times modules). Each dataset is split into 80% training and 20% test subsets, with stratification by label combinations to preserve distribution.

3.2. Dataset and Preprocessing

3.2.1. Pharma Dataset

The pharmaceutical dataset includes employee profiles with features such as age, sex, job designation, reported symptoms, disease duration, and risk level (Low/Moderate/High/Very High). The target is a set of 25 possible Core Training Modules. Categorical features (e.g., sex, designation) are one-hot encoded, while numeric features (e.g., age, disease duration) are min-max scaled. Risk levels are mapped to an ordinal scale (0–3). Symptom descriptions are converted into 384-dimensional numerical vectors using a pre-trained Sentence Transformer model (“all-MiniLM-L6-v2”). The multi-label targets are binarised into 25 binary columns.

3.3. Models

1) **TabNet**: A PyTorch-based interpretable model for tabular data, configured with feature transformer and attentive transformer dimensions $nd=na=16$ $n_d = n_a = 16$ $nd=na=16$, 4 decision steps, and sparse regularisation ($\lambda_{sparse}=10^{-4}$ $\lambda_{lambda}(\text{text}\{\text{sparse}\}) = 10^{-4}$ $\lambda_{sparse}=10^{-4}$). Each binary classifier is trained for up to 40 epochs with early stopping (patience = 10), using the Adam optimiser and a batch size of 256.

2) **AutoInt**: A DeepCTR-Torch model using multi-head self-attention to learn high-order feature interactions. Each module's classifier uses embedding dimensions of 8 for categorical features, trained for 10 epochs with binary cross-entropy loss, Adam optimiser, and a batch size of 128.

3) **xDeepFM**: Also from DeepCTR-Torch, xDeepFM combines a Compressed Interaction Network (CIN) with a DNN to capture explicit and implicit feature interactions.

3.4. Evaluation Metrics

- **Subset Accuracy (Pharma Dataset)**: The fraction of samples with exact label set matches.
- **Mean Average Precision (MAP@3, MAP@5)**: Evaluates ranking quality for the top 3 or 5 predicted modules (pharma dataset).
- **ROC AUC (Micro and Macro)**: Measures the trade-off between true and false positive rates (pharma dataset).

A probability threshold of 0.3 is used for all models to balance precision and recall, based on preliminary tuning.

3.5. Results

After training, all three models achieved **excellent performance on the test set**, with the deep interaction models (AutoInt and xDeepFM) achieving a perfect score on almost all metrics. **Table 2** summarizes key evaluation metrics for each model on the test set (with all values reported on the 0–1 scale). We also provide visual comparisons via confusion matrices and ROC curves for the models.

Table 2: Summary of evaluation metrics on the test set for each model (25-label classification).

Model	Subset Accuracy	Micro F1	Macro F1	Micro AUC	Macro AUC
TabNet	0.8544	0.9591	0.9200	0.9983	0.9779

AutoInt	1.0000	1.0000	1.0000	1.0000	1.0000
xDeepFM	1.0000	1.0000	1.0000	1.0000	1.0000

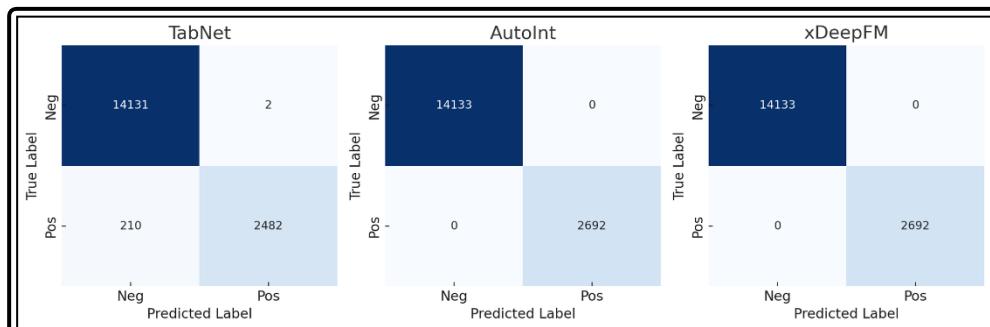
TabNet Performance: The TabNet model predicted the correct set of training modules for about 85.44% of test instances exactly. In other words, roughly 14.5% of employees had at least one module missing or an extra module in TabNet's predictions. Nevertheless, TabNet's *micro-averaged F1* was 0.959, indicating that overall it correctly identified the vast majority of individual module requirements. Notably, TabNet achieved an extremely high *micro-precision* (~0.999), but a slightly lower *micro-recall* (~0.922).

This implies TabNet was very conservative in its predictions almost every module it predicted was truly needed (virtually no false positives), but it did miss some modules that should have been recommended (false negatives). The *macro F1* of 0.920 suggests that performance was consistently strong across most modules, though it could indicate that a few less common modules had lower recall. The *macro-average AUC* for TabNet was 0.978, and the *micro-average AUC* was 0.998, indicating excellent ranking performance (the model's confidence scores were able to nearly perfectly discriminate positives vs. negatives when considering all labels overall). In summary, TabNet provided highly precise recommendations with a small number of missed module predictions.

AutoInt Performance: The AutoInt model achieved *perfect scores* on all evaluated metrics on the test set. It obtained a subset accuracy of 100%, meaning it predicted the exact correct set of modules for every single test instance. Correspondingly, *micro* and *macro F1* scores were 1.0, and precision/recall were 1.0 as well. In fact, AutoInt did not produce a single incorrect module prediction – no false positives or false negatives were observed in the test results. The ROC curves for AutoInt were essentially ideal (AUC = 1.000). This indicates that the AutoInt model was able to fit the training data patterns so well that it generalized (or perhaps **overfitted**, see Discussion) to the test set without any errors. During training, we observed that AutoInt's validation loss dropped rapidly; by a few epochs in, the model had driven the binary cross-entropy loss to near-zero for each label, reflecting how it essentially learned a near-deterministic mapping from features to each module label. The perfect performance suggests that the feature interactions relevant to module assignment were effectively captured by AutoInt's self-attention mechanism, allowing it to distinguish all 25 labels with no confusion.

xDeepFM Performance: The xDeepFM model's results on the test set were **identical to AutoInt's**, with a subset accuracy of 100% and 1.0 on all precision, recall, F1, and AUC metrics. xDeepFM perfectly predicted every required training module for every test sample. This parity in performance suggests that xDeepFM, which combines explicit feature interaction modeling (via the CIN) with deep neural network components, was equally capable of learning the complex relationships in the data. Like AutoInt, the xDeepFM model had no false positives or false negatives on the test set.

Training logs showed that xDeepFM also converged very quickly to a near-zero loss within ~5–6 epochs for most labels, the loss and error rate were essentially zero. The explicit cross features captured by the CIN did not provide a measurable advantage over AutoInt in terms of final accuracy here, likely because the problem was learned to perfection by both; however,



xDeepFM's ability to memorize or represent the necessary decision boundaries was evidently on par with AutoInt for this dataset.

Figure 3. Confusion matrices for each model's predictions on the test set (aggregated over all 25 labels). Each confusion matrix is a 2×2 layout of **Actual vs. Predicted** outcomes, where "Pos" refers to a module being required and "Neg" means not required. The TabNet model (left) shows a handful of errors: it missed some modules (210 false negatives) and incorrectly predicted 2 modules that were not actually needed (false positives). In contrast, AutoInt (center) and xDeepFM (right) achieved perfect classification with zero errors – all actual required modules were predicted (no false negatives) and no unnecessary modules were predicted (no false positives). The stark difference in off-diagonal values highlights that TabNet had high precision but slightly lower recall, whereas the other two models had both precision and recall = 1.0 on the testset.

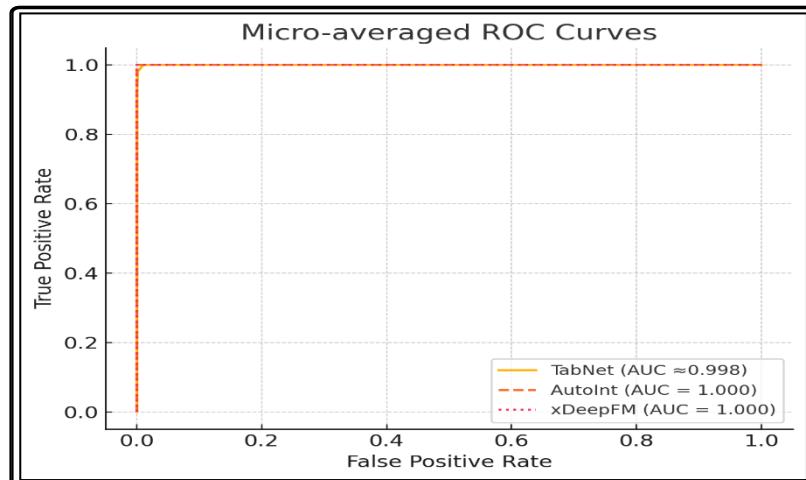


Figure 4. Micro-averaged ROC curves on the test set for TabNet, AutoInt, and xDeepFM. All three models demonstrate extremely strong ROC performance, with curves near the top-left corner of the plot. AutoInt and xDeepFM (dashed red and dotted pink lines, which overlap) achieved a perfect AUC of 1.0, resulting in an almost square-shaped ROC curve that goes straight up (TPR = 1.0 at FPR = 0). TabNet's ROC curve (solid orange line) is also very close to the ideal, with a micro-AUC ≈ 0.998 . It is stoahigh true positive rate with only an negligible increase in false positive rate. Only a tiny gap is visible between TabNet's curve and the perfect classifier line (and it is almost indistinguishable at the scale of the full plot). This indicates that TabNet's score estimates were highly discriminative – for almost all pairs of an actual required module vs. an unrelated module, TabNet ranked the required one higher. In essence, Figure 4 confirms that all models separate positive and negative labels nearly perfectly, with TabNet being just shy of the absolute ideal line. Beyond these overall metrics, we also evaluated the ranking-oriented measures MAP@3 and MAP@5. All models achieved a mean average precision of 1.0 at both cutoffs – this is unsurprising given that each instance has at most 4 true modules and the models were correctly identifying those modules. In TabNet's case, the MAP@3 = MAP@5 = 1.0 suggests that even when it missed a module at threshold 0.3, that module was still ranked within the top 5 predictions for that instance (hence the average precision remained perfect). In practical terms, if one were to recommend, say, 3 or 5 modules per employee, TabNet would still successfully include all the truly needed ones in those top suggestions, despite its few misses at the strict threshold. AutoInt and xDeepFM, of course, trivially achieved perfect MAPs since they had no misses at all.

4. CONCLUSION

TabNet offers a dependable baseline with a subset accuracy of 85.4 per cent and a micro-AUC of approximately 0.998, trading off a recall of about 0.922 for near-perfect precision (≈ 0.999) a sensible compromise in contexts where false positives are costly and can be offset by top-N ranking. In contrast, AutoInt and xDeepFM both secured a flawless 100 per cent across subset accuracy, F1-scores and AUC, demonstrating their prowess at modelling intricate feature interactions, although such perfection on a single dataset prompts caution regarding potential overfitting in more diverse environments. Collectively, these outcomes highlight the transformative promise of AI-driven, personalised training within pharmaceutical manufacturing and point towards a hybrid deployment: leveraging TabNet's conservative precision for core recommendations, supplementing with AutoInt or xDeepFM

for exhaustive coverage, and underpinning both with continuous validation, cross-site testing and adaptive thresholding to ensure sustained robustness and relevance.

REFERENCES

- [1] M. Sarkis, A. Bernardi, N. Shah, and M. M. Papathanasiou, "Emerging Challenges and Opportunities in Pharmaceutical Manufacturing and Distribution," *Processes*, vol. 9, no. 3, p. 457, Mar. 2021, doi: 10.3390/pr9030457.
- [2] S. A. Hout, *Manufacturing of Quality Oral Drug Products*. Boca Raton: CRC Press, 2022. doi: 10.1201/9781003224716.
- [3] A. Ryan, "Human error, human factors and production ergonomics. A discussion from the perspective of biopharmaceutical manufacturing," *Lev. 3*, pp. 1-34, 2025, [Online]. Available: <https://arrow.tudublin.ie/cgi/viewcontent.cgi?article=1232&context=level3>
- [4] E. Tompa *et al.*, "Economic burden of work injuries and diseases: a framework and application in five European Union countries," *BMC Public Health*, vol. 21, no. 1, p. 49, Dec. 2021, doi: 10.1186/s12889-020-10050-7.
- [5] C. M. Naidoo, C. L. Obi, and N. M. Mkolo, "Future Trends and Innovations," 2025, pp. 115-140. doi: 10.4018/979-8-3693-9301-7.ch006.
- [6] S. Gheewala, S. Xu, and S. Yeom, *In-depth survey: deep learning in recommender systems—exploring prediction and ranking models, datasets, feature analysis, and emerging trends*, vol. 37, no. 17. Springer London, 2025. doi: 10.1007/s00521-024-10866-z.
- [7] S. Raza *et al.*, "A Comprehensive Review of Recommender Systems: Transitioning from Theory to Practice," 2025, [Online]. Available: <http://arxiv.org/abs/2407.13699>
- [8] "The Future of Pharmaceutical Training: How to Address Top Industry Challenges Head-On." [Online]. Available: <https://knowledgeanywhere.com/articles/the-future-of-pharmaceutical-training-how-to-address-top-industry-challenges-head-on/>
- [9] "Compressed gases in pharmaceutical manufacturing: best practices in microbial monitoring - Quercus Lab." [Online]. Available: <https://quercus.be/compressed-gases-in-pharmaceutical-manufacturing-best-practices-in-microbial-monitoring/>
- [10] K. Bechtold-Peters *et al.*, "Risk-based approach to setting sterile filtration microbial bioburden limits - Focus on biotech-derived products," *Eur. J. Pharm. Biopharm.*, vol. 198, p. 114151, 2024, doi: 10.1016/J.EJPB.2023.11.016.
- [11] "2025 Safety and Regulatory Compliance Trends and Predictions for Pharma and Biotech - IQVIA." [Online]. Available: <https://www.iqvia.com/library/white-papers/2025-safety-and-regulatory-compliance-trends-and-predictions-for-pharma-and-biotech>
- [12] "Hazardous Drugs - Overview | Occupational Safety and Health Administration." [Online]. Available: <https://www.osha.gov/hazardous-drugs>
- [13] "Exponent: Making Work Around Flammable and Combustible Liquids Safer." [Online]. Available: <https://www.exponent.com/article/making-work-around-flammable-combustible-liquids-safer>
- [14] "Chemical Hazards and Toxic Substances - Overview | Occupational Safety and Health Administration." [Online]. Available: <https://www.osha.gov/chemical-hazards>
- [15] H. Chawla *et al.*, "A comprehensive review of microbial contamination in the indoor environment: sources, sampling, health risks, and mitigation strategies," *Front. Public Heal.*, vol. 11, Nov. 2023, doi: 10.3389/fpubh.2023.1285393.
- [16] T. Hague, "Carbon monoxide; Health-based occupational exposure limit," 2024.
- [17] A. Harper and J. Croft-Baker, "Carbon monoxide poisoning : undetected," *Age Ageing*, vol. 33, no. 2, pp. 105-109, 2012, [Online]. Available: <http://ageing.oxfordjournals.org/content/33/2/105.full.pdf+html>
- [18] "Top Safety Risks in Pharmaceutical Manufacturing." [Online]. Available: <https://www.triumvirate.com/blog/top-safety-risks-pharmaceutical-manufacturing>
- [19] S. Dobbins and K. Knight, *Protecting workers from ultraviolet radiation in sunlight*, vol. 17, no. 6. 2001.
- [20] "Physical Hazards and Risks | International Labour Organization." [Online]. Available: <https://www.ilo.org/topics/safety-and-health-work/physical-hazards-and-risks>
- [21] "Heat - Heat Hazard Recognition | Occupational Safety and Health Administration." [Online]. Available: <https://www.osha.gov/heat-exposure/hazards>
- [22] "Contamination, Cross-Contamination, And Mix-Ups In GMP | GMP Insiders." [Online]. Available: <https://gmpinsiders.com/contamination-cross-contamination-and-mix-ups-in-pharmaceutical-manufacturing/>
- [23] "Pharmaceutical Industry." [Online]. Available: <https://www.iloencyclopaedia.org/part-xii-57503/pharmaceutical-industry>
- [24] "eCFR :: 21 CFR Part 211 ~ Current Good Manufacturing Practice for Finished Pharmaceuticals." [Online]. Available: <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211>
- [25] "FDA Pharmaceutical Risk Evaluation and Mitigation Strategies Guid." [Online]. Available: <https://natlawreview.com/article/fda-final-guidance-document-risk-evaluation-and-mitigation-strategies-modifications>
- [26] "NIOSH List of Hazardous Drugs in Healthcare Settings, 2024.," Dec. 2024. doi: 10.26616/NIOSH PUB2025103.
- [27] "Risk Evaluation and Mitigation Strategies | REMS | FDA." [Online]. Available: <https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems>
- [28] J. Miring'u, E. Gatebe, and B. Karanja, "Assessment of the Influence of Safety Training on the Technicians Safety Culture in the Pharmaceutical Manufacturing Industries in Kenya," *J. Heal. Environ. Res.*, vol. 10, no. 4, pp. 134-148, Dec. 2024, doi: 10.11648/j.jher.20241004.15.
- [29] "N95 Respirators, Surgical Masks, Face Masks, and Barrier Face Coverings | FDA." [Online]. Available: https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-surgical-masks-face-masks-and-barrier-face-coverings?utm_source=chatgpt.com
- [30] "1910.134 - Respiratory protection. | Occupational Safety and Health Administration." [Online]. Available: <https://www.osha.gov/laws-regulations/regulations/standardnumber/1910/1910.134?utm>

[31] S. P. Pillai, S. Bradberry, M. Newcomer, T. Pittas, and K. Mathern, "A framework for personal protective equipment use in laboratories : regulatory compliance and employee protection," no. July, pp. 1–9, 2025, doi: 10.3389/fpubh.2025.1586491.

[32] EMA, "ICH guideline Q9 (R1) on quality risk management," *Step 5 - Revis.*, vol. 9, no. January, pp. 1–27, 2023, [Online]. Available: https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-use-ich-guideline-q9-r1-quality-risk-management-step-5-revision-1_en.pdf

[33] J. D. Balian, J. C. Wherry, R. Malhotra, and V. Perentesis, "Roadmap to risk evaluation and mitigation strategies (REMS) success," *Ther. Adv. Drug Saf.*, vol. 1, no. 1, pp. 21–38, Oct. 2010, doi: 10.1177/2042098610381419.

[34] "Predictive Safety Testing Consortium." [Online]. Available: <https://c-path.org/program/predictive-safety-testing-consortium/>

[35] K. E. Trinkley, A. M. Maw, C. H. Torres, A. G. Huebschmann, and R. E. Glasgow, "Applying Implementation Science to Advance Electronic Health Record-Driven Learning Health Systems: Case Studies, Challenges, and Recommendations," *J. Med. Internet Res.*, vol. 26, p. e55472, Oct. 2024, doi: 10.2196/55472.

[36] "Health, Safety, Wellbeing \& Environmental Courses and Online Training | British Safety Council." [Online]. Available: <https://www.britsafe.org/c/training/all-health-safety-environmental-and-wellbeing-courses>

[37] "Personal Protective Equipment (PPE) Training." [Online]. Available: <https://www.highspeedtraining.co.uk/courses/health-and-safety/personal-protective-equipment-training/>

[38] "Health and Safety Training | Johns Hopkins Medicine." [Online]. Available: <https://www.hopkinsmedicine.org/hse/training>