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The emergence of advanced technologies in the pharmacy profession and the need for education: The case of point-of-care sensing systems and 3D printing of pharmaceuticals

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Abstract

Introduction: The pharmacy profession is undergoing significant transformation through the adoption of point-of-care testing (POCT) and three-dimensional (3D) printing of pharmaceuticals. These technologies offer enhanced diagnostic accuracy, faster therapeutic interventions, and the potential for personalized medication regimens. Accordingly, there lies a great need for proper education.

Methods: A comprehensive literature review was conducted to explore the impacts and current educational integration of POCT and 3D printing of pharmaceuticals in the pharmacy profession, and a qualitative analysis was performed.

Results: Through the integration of POCT into community and clinical settings, pharmacists can promptly identify health conditions and provide timely referrals or interventions, ultimately improving patient outcomes. Additionally, 3D printing allows for the creation of highly customized dosage forms, supporting targeted drug delivery and better patient adherence. These innovations necessitate adjustments in pharmacy education to equip future professionals with the requisite clinical and technical skills to provide value to the healthcare system. Pharmacy educators must be current in their knowledge. Curricula must emphasize hands-on experiences, such as simulations and laboratory training, to foster proficiency in using diagnostic devices, interpreting results, and designing bespoke drug formulations. Interprofessional collaboration, policy development, advocacy, and ongoing faculty training are also crucial for ensuring that pharmacists remain at the forefront of technological advancements. This context underscores the importance of weaving these modern tools into educational strategies.

Conclusion: By preparing pharmacists for expanded and more technical roles in healthcare, including diagnostics and medication customization, schools and colleges of pharmacy can propel the profession forward and elevate the standard of patient care in rapidly evolving healthcare environments and improve patient outcomes, thereby providing critical cost savings to the system.
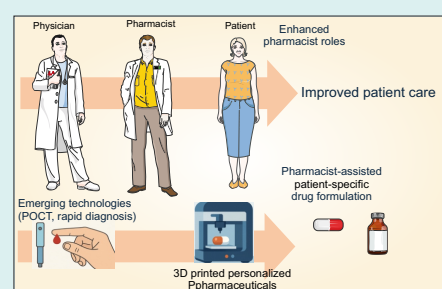
Introduction

Pharmacy education is nascent in response to technological advancements and the expanding role of pharmacists in healthcare.[1] From point-of-care testing (POCT) and sensing systems to novel manufacturing processes such as three-dimensional (3D) printing, these innovations present both opportunities and challenges for pharmacy curricula and professional practice. A growing body of literature underscores the need to integrate new technologies into pharmacy education to meet the changing demands of patient care and prepare future pharmacists for increasingly complex clinical roles.[2,3] This paper provides an overview of how POCT has become integral to pharmacy practice, highlights the potential for 3D printing in pharmaceutical education, and discusses the implications for curriculum design and professional development.

Pharmacy practice has traditionally focused on

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dispensing medications and providing patient counseling. However, in recent years, there has been a marked shift toward more patient-centric and clinically oriented services involving medication optimization and safety.[4] This shift includes administering immunizations, managing chronic diseases, and conducting medication therapy management (MTM) programs.

More recently, pharmacists have begun to adopt POCT services, especially in community settings, to improve patient access to diagnostic testing and improve clinical outcomes.[5] These broader responsibilities require corresponding enhancements in pharmacy education so that future pharmacists are equipped with the necessary skills to interpret clinical data and deliver evidence-based interventions.[6]

Meanwhile, 3D printing (the so-called additive manufacturing), which involves layer-by-layer fabrication of objects from digital models, holds promise for precision and personalized medicine in this patient-centric model.

This forces a necessary revision in the pharmacy curriculum to meet the needs of such precision bioengineered medicines and advances in patient care. For example, bio-GMP laboratories, similar to drug formulation, will be essential for the bioformulation of cell- and/or tissue-based medicines and available to student learners. This review aims to highlight the importance of the integration of emerging technologies in the current pharmacy curriculum for training pharmacists with such expertise. Table 1 summarizes the influence of different disciplines relevant to futuristic pharmacy, the key competencies/skills, and potential impact/applications.

Emerging technologies in pharmacy education and profession

Emerging technologies are rapidly reshaping pharmacy practice, pushing the profession beyond traditional dispensing toward data-driven, patient-centered, and personalized care. This raises the need for pharmacy students to be competent practitioners in these fields. Specifically, POCT can provide real-time clinical insights, while in-pharmacy 3D printers enable on-demand production of customized dosage forms that match individual pharmacogenomic profiles or dynamic therapeutic needs. Artificial intelligence augments these capabilities by predicting adherence risks, optimizing inventory, and guiding precision dosing algorithms. Simulated reality platforms (as virtual, augmented, and mixed approaches) provide immersive skills training that replicates complex clinical scenarios without risking patient safety. Further, blockchain-anchored supply chains bolster drug authenticity and traceability.[22] Collectively, these tools demand new curricular content in coding, quality-by-design, data analytics, and human-factor engineering, preparing graduates to navigate a healthcare landscape where the pharmacist acts simultaneously as

diagnostician, formulator, and informatics specialist. Fig. 1 represents schematic illustrations for emerging technologies in pharmacy education and profession.

Potential benefits and applications of POCT and 3D Printing

The principal advantage of integrating 3D printing into pharmacy education lies in its capacity to deepen students' understanding of pharmaceutical compounding, drug formulation, and personalized medicine. By allowing precise control over drug release profiles, shapes, and dosages, 3D printing can help illustrate the theoretical underpinnings of pharmaceutics in a tangible manner. Additionally, 3D-printed models or devices can serve as valuable educational aids, enabling students to visualize complex anatomical structures or drug delivery mechanisms more effectively than traditional diagrams or static models.

The technology also opens avenues for innovative patient-centered care. Students exposed to 3D printing processes gain firsthand experience in customizing therapy for specific patient needs. For instance, a patient who struggles with traditional pill-swallowing might benefit from a rapidly dissolving 3D-printed oral film with an individualized dose. Pharmacy education that incorporates such experiential learning can pave the way for new roles in advanced practice settings, strengthening the pharmacist's position as a healthcare innovator. Fig. 2 represents the integration benefits of POCT and 3D printing in the pharmacy profession.

Diagnostic transformation via POCT

Point-of-care sensor system testing has recast the pharmacist's role from passive dispenser to active clinician by shrinking the temporal and spatial gaps between specimen collection, result interpretation, and therapeutic decision-making. Modern handheld analyzers quantify biomarkers such as HbA1c, C-reactive protein, Influenza A, Streptococcus, and SARS-CoV-2 antigens within minutes, empowering pharmacists to initiate therapy during the same encounter, sometimes under a physician collaborative practice agreement or protocol. The immediate feedback not only accelerates disease management, reducing downstream transmission, hospital visits, and associated costs, but also strengthens patient engagement, as individuals receive real-time counseling while results are still top-of-mind. In underserved or rural settings, POCT further narrows health-equity gaps by providing greater access and bypassing wait times at centralized laboratories.[1, 23] Collectively, these advances reposition the pharmacy counter as a frontline diagnostic hub that supports chronic-disease monitoring, antimicrobial stewardship, and public-health surveillance.

Table 1. The impacts of different disciplines, key skills, and applications in the transformation of pharmacy profession

Field	Relevance to futuristic pharmacy	Key competencies and skills	Potential impact and applications	Ref.
Point-of-care testing (POCT)	Enables rapid, on-site diagnostic insights, facilitating immediate therapeutic interventions in community and clinical settings	- Proficiency in operating and maintaining POCT devices - Ability to interpret and act upon test results - Knowledge of relevant clinical guidelines and patient counseling	- Early disease detection and rapid intervention - Improved patient follow-up and adherence - Reduced burden on secondary healthcare facilities	2,7
3D printing	Facilitates the creation of customized dosage forms, allowing for targeted drug delivery, improved medication adherence, and adaptation to individual patient needs	- Understanding of 3D printing processes and materials - Skills in designing dosage forms and adjusting drug release profiles - Awareness of regulatory and quality standards	- Personalized medication regimens - Enhanced patient compliance through customized forms - Development of specialized implants and devices	8-10
Personalized formulations	Supports patient-specific therapies through tailored drug concentrations, release profiles, and innovative materials (e.g., bioinks)	- Competence in pharmaceutical compounding and formulation design - Knowledge of pharmacokinetics, pharmacodynamics, and biomaterials - Familiarity with bioinks and novel excipients	- Precision medicine with optimized therapeutic outcomes - Reduced adverse effects via dose individualization - Possibility of on-demand manufacturing for rare or orphan conditions	11
Clinical and technical skills	Integral for handling advanced diagnostic tools, interpreting complex data, and performing specialized procedures in rapidly evolving healthcare settings	- Clinical decision-making and problem-solving - Mastery of advanced laboratory techniques (e.g., molecular diagnostics) - Technical troubleshooting of devices	- Higher accuracy in medication therapy management - Swift adjustment of treatment plans based on diagnostic data - Increased trust and collaboration with other healthcare professionals	-
Interprofessional collaboration	Ensures seamless integration of pharmacists' roles with physicians, nurses, and other healthcare professionals for comprehensive patient care	- Strong communication and team-building skills	- Improved patient outcomes through coordinated care	-
		- Cross-disciplinary understanding of healthcare workflows - Ability to coordinate care and collaborate on complex patient cases	- Enhanced workflow efficiency in clinical settings - Shared responsibility in designing and evaluating treatment regimens	
Policy and regulatory affairs	Governs ethical deployment of novel technologies like POCT and 3D printing in pharmacy practice, including licensure, scope of practice, and quality assurance	- Knowledge of healthcare policies and regulations - Familiarity with intellectual property and device certification processes - Advocacy skills for shaping practice standards	- Compliance with local and global regulations - Protection of patient safety and privacy - Facilitation of swift technology adoption and standardization - Pharmaceutical industry	12-14
Faculty training and education	Essential for updating curricula to include hands-on experiences with emerging technologies, ensuring that upcoming pharmacy professionals are well-prepared	- Curriculum development and instructional design - Technological proficiency (3D printers, POCT devices) - Continuous professional development and research integration	- Production of highly skilled pharmacy graduates - Ongoing innovation in teaching methods - Stronger research collaborations and industry partnerships	15-18
Data analytics and digital health	Critical for analyzing large sets of patient data from POCT devices and 3D-printed medication outcomes, leading to evidence-based decisions and optimized patient care	- Competence in data interpretation and statistical analysis - Familiarity with electronic health record systems - Ability to safeguard patient data (cybersecurity and privacy)	- Personalized, data-driven interventions - Enhanced tracking of patient outcomes for continuous improvement - Innovation in remote and telehealth pharmacy services	19-21

Point-of-care testing and biosensing systems, state of the science, developing practicalities, and their educational value in pharmacy education

POCT refers to diagnostic tests that are performed near the site of patient care, offering rapid results that can guide clinical decision-making.[1] Numerous studies have demonstrated the effectiveness of such tests when integrated into pharmacy practice. For instance, Sun et al proposed affordable colorimetric approaches for the on-site detection of metal ions,[3] while Zhang et al designed a miniaturized colorimetric-photoacoustic device capable of detecting ascorbic acid in food.[24] Although these studies primarily address diagnostic processes in broader contexts, they illustrate the portability and speed inherent in POCT systems—characteristics that have direct applicability in a pharmacy setting.

Pharmacy curricula that incorporate POCT often include hands-on laboratory workshops, simulations, and interprofessional education.[6] From an educational standpoint, exposing student pharmacists to POCT has
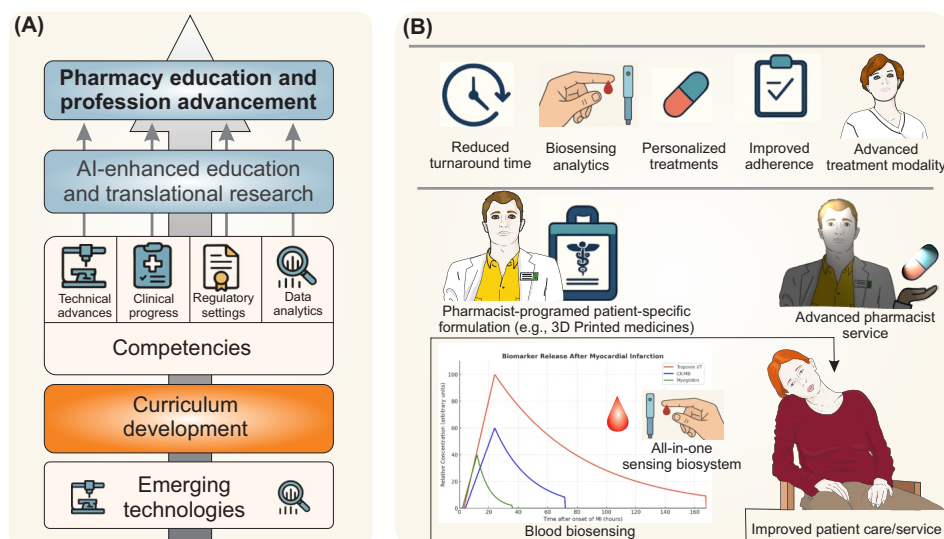
Fig. 1. Emerging technologies in pharmacy education and profession. A) Integration of emerging technologies and their competencies in pharmacy education and profession. B) The impacts of POCT and 3D printing of medications.
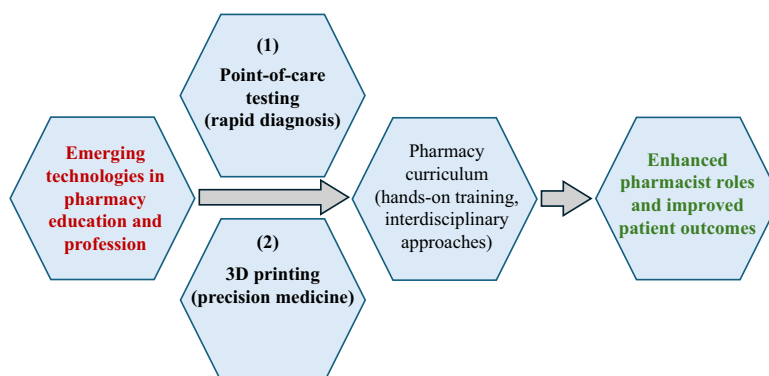

Fig. 2. The integration benefits of POCT and 3D printing in the pharmacy profession.

several benefits. First, practical involvement with POCT technologies fosters clinical reasoning with emerging technologies, as students must understand not only how to perform a test but also how to interpret results accurately. Second, POCT training equips students to navigate various clinical scenarios that require immediate therapeutic interventions, such as managing potential infections.[23] Third, it introduces students to collaborative healthcare, whereby pharmacists coordinate with other professionals (e.g., physicians and nurses) and guide patients effectively based on on-site test findings.[25]

Kherghehpoush and McKeirnan highlight how community pharmacy-based screening for HIV and hepatitis C can broaden students' understanding of infectious disease management while also refining their communication and counseling skills.[26] The success of such programs suggests that incorporating clinical skill training with POCT in the education of future pharmacists can substantially enhance professional readiness and patient care outcomes.[27] Further, pharmacy education is increasingly integrating innovative diagnostic technologies into its curricula, particularly POCT, and biosensors that enable rapid, accurate, and minimally invasive testing. These biosensors, which include electrochemical and optical platforms, are revolutionizing how pharmacists learn about disease diagnosis, therapeutic monitoring, and personalized treatment strategies.[28] Their high specificity, sensitivity, and speed make them essential for early detection of critical biomarkers in a variety of diseases, such as cancer and kidney disorders.[29,30]

In the context of oncology, research has showcased immunosensors tailored to detect biomarkers like carcinoembryonic antigen and CA 15-3 for detection of cancers, including colon, breast, and lung.[31,32] By offering ultra-low limits of detection, these devices give future pharmacists a practical illustration of how early disease diagnosis can be translated from bench to bedside. Modern biosensors, especially electrochemical immunosensors, exemplify how nanotechnology and biorecognition elements converge to enable rapid, ultrasensitive detection of disease biomarkers. For instance, sandwich-style

immunosensors enhanced by nanoparticles can detect carcinoembryonic antigen (CEA) at concentrations as low as 58 fg/mL, demonstrating unprecedented specificity and sensitivity.[28] Similarly, point-of-care detection of key cancer biomarkers, such as CA 15-3 and CA-125, has been achieved using electrochemical platforms with detection limits of 15×10^{-6} U/mL and 0.0016 U/mL, respectively.[29,32] The capacity of these biosensors to detect minuscule amounts of markers enhances early diagnosis, subsequently improving therapeutic outcomes and overall patient survival rates. From a nephrology perspective, early detection of kidney dysfunction is vital to prevent disease progression,[30] including biosensors that measure cystatin C levels offer a promising avenue for rapid and precise assessment of renal function, enabling pharmacists to guide appropriate interventions in a timely manner. Moreover, immunosensors designed for metabolic pathway assessment, such as the tryptophan-kynurenine pathway, reveal cancer cell immune evasion mechanisms and thereby support individualized immunotherapy decisions.[33] Incorporating these advancements into pharmacy education fosters a workforce adept at harnessing point-of-care diagnostics. Trainees not only learn to interpret data from biosensors but also to communicate these findings to multidisciplinary teams and patients. By mastering biosensor technologies, graduates are empowered to improve medication therapy management, expedite diagnostic testing, and optimize patient-centric care in various clinical and community settings. As such, the integration of cutting-edge biosensor methodologies and POCT within pharmacy education is instrumental in shaping the next generation of pharmacists to be key contributors to precision medicine and public health.

Personalized drug formulation by 3D printing: state of the science, developing practicalities, and their educational value

Additive manufacturing brings precision pharmaceutics to the community level by allowing dose, geometry, and release profile to be customized on demand. Powder-bed and semisolid-extrusion printers now yield highly porous printlets that dissolve rapidly for dysphagic patients, multilayer tablets combining incompatible APIs, and pediatric chewables calibrated in one-tenth-milligram increments. Layer-by-layer fabrication also facilitates complex internal lattice structures, enabling zero-order or pulsatile release kinetics that were previously achievable only in industrial settings. When linked with pharmacogenomic or therapeutic-drug-monitoring data, 3D printing enables genuinely personalized regimens. Examples include warfarin titration tablets printed to the exact milligram or transplant patients receiving tacrolimus micro-doses that match real-time trough levels. The technology, therefore, transforms the pharmacist from a distributor of fixed-strength products into a point-of-care manufacturer of bespoke medicines.[34-36]

Of note, advances in additive manufacturing now allow drug developers to treat each formulation as a malleable digital object rather than a fixed product. This is an outlook that underpins the emerging field of personalized point-of-care pharmacy. Three emerging technological themes stand out. First, multi-material and multilayer printing give pharmacists new levers for controlling dose distribution and release profiles. In a non-pharmaceutical exemplar, Li et al stacked three functional layers (i.e., heater, thermochromic film, and infrared pattern) inside a 140 μm flexible laminate, in which the internal heater raised the surface to 65 °C within 12 seconds, demonstrating that thermal events can be triggered without external hardware.[37] Translated to medicines, the same architecture could localize heat-activated drug reservoirs inside dissolvable films, enabling on-skin titration without bulky devices. Second, geometric precision at the microscale and nanoscale can be used to program drug kinetics. Recently, researchers achieved chiral quantum-dot stacks that generated an eight-fold photoluminescence enhancement and a circular dichroism of > 20 ° simply by offsetting 200 nm layers.[38] By analogy, offsetting drug-laden strata inside a printable "polypill" might let formulators vary surface area-to-volume ratios or create clockwise versus counter-clockwise helices that modulate dissolution under laminar flow in the gut. Evidence that load-bearing accuracy does not have to be sacrificed comes from Zhang et al, whose continuous-fiber thermoplastic trusses reached an equivalent compression modulus of 402 MPa at a skeletal density of only 1.45 %.[39] Such lightweight reinforcement could be embedded in intragastric or intranasal implants without compromising patient comfort. Third, mechanical tuning across wide modulus ranges enables tissue-matched and patient-matched dosage forms. Hong et al printed hydrogel microgel/overlay pairs whose elastic moduli spanned 1.7–31.6 kPa.[40] They showed that macrophage spheroid formation and M1/M2 polarization shifted measurably across that gradient, underscoring the biological impact of subtle mechanical cues. For pediatric or geriatric tablets, similar tuning could reconcile the need for structural integrity during handling with rapid disintegration once swallowed. Wattanaanek et al reported on another quantitative anchor. These researchers showed that calcium-phosphate/sulfate scaffolds with 20 wt % ceramic phase could result in a compressive strength of 5.6 MPa, which is well within cancellous-bone territory while supporting MC3T3-E1 proliferation at day 7. The result hints that printable matrices can be strong enough for load-bearing yet porous enough for cell ingress, a duality crucial to long-acting depot systems.[41]

Layer-by-layer deposition, however, introduces path-length mismatches and residual stresses that can

perturb content uniformity. Nakajima and Matsuzaki showed that a 6° filament twist minimized the width variation of carbon-fiber plies in curved laminates, reducing cross-sectional error below 0.05 mm. Such optimization is directly relevant to curved orodispersible films intended to sit against the palate.[42] At the microscale, Dai et al modelled a selective-laser-melted AlN/AlSi10Mg composite. They found that the dominant heat-flow vector flips from vertical to horizontal after five deposited layers, by which the extension API stability can change continuously during a build and must be captured in process-analytical technology.[43]

Collectively, these quantitative demonstrations outside traditional pharmaceutics foreshadow a near-term future in which pharmacists exploit the same engineering knobs (e.g., multilayer stacking, mechanical anisotropy, nanoscale patterning) to print medicines whose dose, shape and performance are matched to the physiology and lifestyle of each patient. The challenge now is less about inventing new printers than about translating proven material and process controls into pharmaceutically acceptable inks and establishing regulatory pathways that treat every build file as a controlled but modifiable master record.

While POCT has garnered significant attention as a valuable diagnostic tool in pharmacy settings, 3D printing (also referred to as additive manufacturing) is emerging as another pivotal technology. Although none of the cited studies explicitly address 3D printing in pharmacy, the rapid innovation trajectory in pharmaceutical sciences indicates that 3D printing will likely become more prominent.[44] In particular, 3D printing has been recognized for its potential to individualize medication dosages, create complex drug formulations, and fabricate pharmaceutical devices with high levels of customization. In this regard, faculty might face a multifaceted learning curve when asked to teach technologies such as POCT, 3D drug printing, and other emerging advancements.

First, few pharmacy programs cover additive manufacturing, clinical genomics, or near-patient diagnostics. In most programs, the baseline technical literacy appears to be uneven. Faculties also lack such capacity. Bringing them up to speed demands extensive continuing-education courses, vendor-specific certificates, or even sabbaticals in engineering or clinical laboratories – a commitment that may collide with already heavy teaching, research, and service loads.

Second, hands-on mastery requires access to functioning printers, clean-room space, and a CLIA-waived device. Nonetheless, many colleges lack the capital budget or infrastructure (e.g., ventilation, GMP-compliant workflows) to create and maintain these specialized environments. Additionally, the value may not be viewed as universal at this current time.

Third, curricular time is finite, weaving new competencies into skills labs or therapeutics modules often forces difficult trade-offs with legacy content, and consensus on what to trim is challenging. Also, the issue arises where in the curriculum this is best taught, and what supplemental instruction should be complemented.

Fourth, aligning pedagogy with challenging regulatory frameworks adds complexity. Hence, faculty must teach not only device operation but also documentation practices, process validation, and quality-control metrics that mirror the FDA/EMA standards, which are areas outside traditional pharmacy expertise.

Fifth, educational assessment tools are still emerging; developing objective structured clinical examinations (OSCEs), simulation scenarios, and rubric-based evaluations that accurately capture students' diagnostic accuracy or printing proficiency can take multiple semesters of iteration.

Finally, many faculty might feel unprepared to lead these endeavors as the technology is state-of-the-art, and many institutions might struggle to reward the extra effort of faculty as promotion criteria seldom credit time spent on technology acquisition, protocol writing, or interdepartmental coordination. Such effects might create disincentives and delays for faculty to champion these innovations unless leadership embeds them in strategic plans and workload models and provides adequate training and development. Perhaps, an innovative solution might be certificate-based education after graduation for faculty.[44]

Contemporary considerations for POCT and 3D printing

Point-of-care sensory system testing and on-demand 3D printing operate on the same transformative principle, moving critical health-care functions from distant facilities directly into the pharmacy, providing immediate and widespread access, even though they are yet to be refined at different steps of the therapeutic pathway.[45,46] With POCT, pharmacists obtain diagnostic data within minutes, enabling same-visit therapeutic decisions that replace the traditional lag created by off-site laboratories. With 3D printing, pharmacists fabricate patient-specific medicines – whether low-dose pediatric formulations, polypills, or modified-release designs – within hours, eliminating lengthy wait times for special-order products or dose splitting that can compromise accuracy. Together, these technologies substantially improve the diagnosis-to-treatment timeline, extend the pharmacist's clinical scope, and support genuine precision medicine by pairing real-time analytics with custom-built drug fabrication in one accessible location.[46] Compared with centralized testing and conventional tablet production, these technologies collectively shorten time to treatment, enhance precision, and position pharmacists at the center of personalized

Table 2. Comparison of POCT and 3D printing with the traditional methods

Criterion	POCT	3D printing of medicines	Traditional methods	Unique value added	Ref.
Primary use	Fast, near-patient diagnostics (e.g., HbA1c, influenza, INR)	On-demand fabrication of dosage forms with tailored dose, shape, or release	Central laboratory testing/mass tablet manufacturing	Moves critical steps (diagnosis or compounding) from remote facilities to the pharmacy counter, shortening therapeutic cycles	46-51
Turn-around time	≤ 5–30 min from sample to result	Hours to < 1 day from order to finished dose	1–3 days for sending-out labs; weeks–months for industrial batch manufacturing	Accelerates clinical decision-making (POCT) and eliminates wait-time for special-strength or pediatric doses (3DP)	46,49,51
Location of operation	Community or hospital pharmacies using CLIA-waived devices	Hospital or academic pharmacy clean room or Bio-GMP pod	Central labs / off-site compounding; large GMP plants	Decentralized services, improving access in rural or understaffed settings	52,53
Personalization capability	Limited—interprets patient status, but does not change drug itself	High—precise milligram-level dose titration, geometry-controlled release, polypills	Minimal—fixed commercial strengths; split/crush introduces error	True precision therapeutics: diagnostic result + bespoke dose produced under one roof	46,51
Typical capital outlay	US $2 k–20 k per device	US $20 k–250 k per printer + formulation software	N/A to individual pharmacy	Lower entry cost for diagnostics; scalable investment for compounding innovation	49,54
Regulatory framework	CLIA-waived/moderate complexity; state pharmacy boards	FDA/CDER guidance (2017); EMA reflection paper (2023) on personalized meds	Established compendial standards; ANDA/NDA pathways	Provides evolving, pharmacy-adapted pathways versus rigid industrial rules	49,52,54,55
Staff skill set required	Sample handling, quality control, CLIA documentation	CAD, extrusion or powder-bed operation, in-process QA	Routine dispensing, lab logistics	Drives new competencies that expand pharmacists' clinical and technological roles	56
Key implementation barriers	Reimbursement variability; QC proficiency maintenance	Raw-material sourcing, printer validation, stability data, cost recovery	Scale inflexibility, long supply chain	Overcomes limitations of batch economics and slow feedback loops	

GMP: Good Manufacturing Practice, Bio-GMP: biological GMP, CLIA: Clinical Laboratory Improvement Amendments, FDA: Food and Drug Administration (U.S.), CDER: Center for Drug Evaluation and Research, EMA: European Medicines Agency, NDA: Abbreviated New Drug Application, ANDA: Abbreviated NDA, CAD: Computer aided design.

care. Table 2 compares POCT and 3D printing to traditional methods or other technologies, clarifying their unique value in pharmacy.

United States FDA and European Union EMA pathways for POCTs

In the U.S., most pharmacy-run POCT systems enter the market as medical devices via 510(k) clearance pathway or, when no suitable predicate exists, a De Novo route. After clearance, sponsors may further file a CLIA-waiver application. To succeed, they must show that untrained users in two independent sites can operate the device safely and similarly to generate results equivalent to a central laboratory.

FDA's most recent performance metrics put the mean 510(k) decision time at roughly 150 days and dual 510(k)/CLIA submissions at a similar scale, while De Novo reviews average just over 300 days.[57,58]

Europe regulates the same products under the In-Vitro Diagnostic Regulation (EU) 2017/746. Near-patient assays typically fall in Class C, which obliges manufacturers to undergo a full Notified-Body conformity assessment that commonly spans 9–12 months; transitional provisions adopted in 2024 extend mandatory IVDR compliance for legacy devices to 2027-2029 to relieve capacity constraints.[59,60]

Across both regions, the principal post-market challenges are economic rather than technical. As a result, pharmacies must finance ongoing quality-control programs and negotiate reimbursement mechanisms that still favor centralized testing.

For additively manufactured medicines, FDA currently applies existing pharmaceutical frameworks while it refines a bespoke policy. Centrally produced products, exemplified by the porous levetiracetam tablet Spritam®, follow the standard NDA or ANDA path, supported by the 2017 guidance titled "Technical Considerations for Additive-Manufactured Medical Devices," which outlines chemistry-manufacturing-controls expectations for layer-by-layer builds.[61]

To stimulate innovation, the agency launched an Advanced Manufacturing Technology (AMT) designation program in 2024 that offers enhanced dialogue and prioritized review for distributed-manufacturing platforms, including in-pharmacy printers.[62] A separate 2023 discussion paper explores how point-of-care printing might be regulated, suggesting models that range from full NDA oversight to a new "production site" registration category.[63] The EMA has flagged similar issues: its network strategy documents and policy analyses identify 3-D

printing as a priority technology and note that personalized printlets will still require a Marketing Authorization unless they are prepared under tightly defined magistral exemptions, leaving Member States to harmonize Good Manufacturing Practice expectations.[64,65] Review clocks seems to remain comparable to the traditional products, i.e., 10 months (standard), or 6 months (priority) for an NDA in the U.S., and 210 days scientific time in the EU's centralized procedure. However, both agencies now ask sponsors to justify how they will define "batch," monitor in-process layer quality, and prove long-term stability for highly porous dosage forms. Such chemistry and GMP hurdles, rather than dossier timelines, are the rate-limiting steps for bringing pharmacy-printed medicines to clinical practice.

Comparative overview of commonly used 3D printing methods in pharmaceutical formulations

Some 3D printing methods are commonly used in the printing process of pharmaceuticals. Depending on the formulation process, different 3D printing techniques can be implemented. The process relies on various techniques, each with distinct advantages, limitations, and application domains.[35] Among the most prominent methods are fused deposition modeling (FDM), selective laser sintering (SLS), and inkjet printing.[66]

Of these, FDM uses a heated nozzle to melt and deposit thermoplastic filaments that may contain active pharmaceutical ingredients (APIs). It is widely adopted due to the availability of low-cost printers and straightforward processes.[67] FDM allows for high drug-loading capacity and the fabrication of polypills for personalized therapies.[68] However, the elevated processing temperature can degrade heat-sensitive drugs and require pre-processing of filaments (i.e., via hot-melt extrusion), which can introduce complexity.[69] FDM has been especially useful for solid oral dosage forms, pediatric formulations, and implants.[14]

Notably, SLS, as a powder-based process, implements a laser to selectively fuse powdered materials layer by layer.[70] One advantage is that the unfused powder acts as a support structure, making it possible to create complex shapes without additional scaffolding.[71] This opens the door for intricate geometries and multi-layer drug delivery devices. Nonetheless, the high cost of laser equipment and the need for carefully controlled powder handling can be drawbacks.[66] SLS is frequently explored for implantable devices, novel controlled-release systems, and drug-loaded scaffolds.[71]

Inkjet Printing, on the other hand, precisely deposits small droplets of a solution or suspension containing the drug and excipients onto a substrate.[8] It offers exceptional control over dose accuracy and is well-suited for rapidly disintegrating films or personalized dosage forms.[72] This method also minimizes material waste. The primary challenges are the strict viscosity and surface tension requirements of the ink, as well as the relatively slow printing speed.[70] Altogether, of the FDM, SLS, and Inkjet printing methods, each presents unique benefits for personalized medicine, complex geometries, and controlled release. As research advances, it is increasingly evident that a combination of material innovation, process optimization, and regulatory clarity will drive these technologies toward broader adoption in pharmaceutical education and practice.

The first real-world evidence comes from Spritam® (levetiracetam), the epilepsy medicine that became the inaugural FDA-approved 3D-printed tablet in 2015. Produced with Aprecia's ZipDose® powder-bed technology, the printlets possess a highly porous architecture that disperses in seconds with a sip of water, removing a well-known swallowing barrier for high-strength antiepileptic drugs. Post-approval pharmacovigilance reports compiled by hospital pharmacies have linked the rapid-dissolve profile to better dose completion in pediatric and geriatric populations and fewer crushing/splitting errors during medication administration.[50,73] Clinicians also point to the formulation's precise layer-by-layer dosing as an aid to therapeutic drug monitoring, because each unit contains the full labeled amount without the variability sometimes seen in split tablets. Together, these operational gains illustrate how an FDA-cleared 3D-printed product can outperform conventional solid doses in daily pharmacy practice. Complementary data are emerging from hospital-based trials that fabricate personalized medicines on site. In Finland, semisolid-extrusion printers were used to create orodispersible warfarin films in four pediatric strengths (0.1–2 mg) and compared head-to-head with the pharmacy's traditional oral-powder sachets. The printed films met European Pharmacopoeia content-uniformity limits. The products showed tighter dose accuracy than the compounded powders while remaining physically stable for one month and fully dispersing in water. These products are attributed to having streamlined anticoagulation management on the pediatric ward. A separate single-center crossover study in Spain provided chewable amino-acid printlets for children with inherited metabolic disorders. Remarkably, the 3D-printed formulations kept plasma citrulline and branched-chain amino-acid levels within target ranges and were preferred in taste tests, supporting improved adherence.[46,51]

Challenges and considerations

Despite the promise of 3D printing, several practical issues must be addressed before it becomes widely integrated in pharmacy education. The cost of acquiring and maintaining the necessary hardware, software, and materials can be substantial.[27] Additionally, establishing robust quality assurance protocols and ensuring regulatory

compliance require a comprehensive framework that spans both academic institutions and licensing bodies.[25]

Training faculty and students to use 3D printing equipment effectively is also pivotal. Educators may need to develop specialized teaching modules and collaborate with experts in engineering or industrial design to incorporate best practices.[4] Similar to POCT training, where students must learn how to operate devices and interpret results accurately,[2] 3D printing education would require a thorough understanding of digital design software, polymer science, and drug stability considerations.

Implications for curriculum development

As both POCT and 3D printing gain traction, pharmacy education must evolve to include competencies that align with these emerging technologies. Curricula may incorporate interdisciplinary coursework covering diagnostics, clinical interpretation, product design, and patient-centered services. For POCT, integrating classroom learning with hands-on experience ensures that students are prepared to perform and interpret tests confidently upon entering practice.[6] For 3D printing, schools could offer laboratory-based modules that guide students through the design, production, and testing of printed dosage forms, thereby connecting theoretical content with real-world applications.[44]

Collaboration with industry, regulatory agencies, and professional organizations is essential for shaping educational standards. Similar to how organizations have advocated for increased POCT training to expand pharmacists' clinical impact,[2] it is anticipated that these same entities will promote policies and guidelines around 3D printing to ensure safety, efficacy, and ethical considerations.[1] Incorporating these guidelines into coursework and experiential learning helps students remain up to date with evolving practice standards.

Finally, the incorporation of POCT and 3D printing must be undertaken with attention to resource allocation and faculty expertise.[74] While advanced technologies can enhance learning, they also require investment in physical infrastructure, curriculum redesign, and continuing education for instructors. Optimizing these elements ensures that the next generation of pharmacists is well-equipped to harness the full potential of emerging tools in patient care.

The integration of POCT and 3D printing into pharmacy education underscores the ongoing transformation of the profession. Of these, POCT has already demonstrated its value in expanding pharmacists' roles, from infectious disease screening to chronic disease management.[26,27] Meanwhile, 3D printing stands at the frontier of personalized medicine and drug formulation, offering students an immersive way to understand complex pharmaceutical concepts and novel manufacturing processes.[44] By aligning educational practices with these advancing technologies, pharmacy programs can better prepare graduates to meet contemporary healthcare challenges, improve patient outcomes, and spearhead innovations in drug delivery and diagnostics. As these technologies continue to evolve, ongoing collaboration between educators, regulatory bodies, and practice leaders will be essential to ensure that the pharmacy profession remains responsive to the needs of patients and the broader healthcare system.

Key highlights in 3D and 4D printing to regenerate tissues

In precision regenerative medicine, 3D and 4D printing are rapidly revolutionizing tissue regeneration by enabling the fabrication of complex, patient-specific constructs that closely mimic native tissue architecture. Traditional 3D bioprinting allows for the accurate placement of cells and biomaterials—often hydrogels like alginate, collagen, or PEG-based polymers—to form scaffolds with tailored mechanical properties and biological cues.[75] A notable success includes achieving a compressive modulus of 0.38 MPa in double-network hydrogels, sufficient for many soft tissues.[76] Another significant advance is the incorporation of nanomaterials (e.g., graphene oxide, zinc-doped hydroxyapatite) for enhancing both osteogenic differentiation and antibacterial activity by up to 3.4 times.[77] In contrast, 4D printing introduces a temporal component whereby materials or constructs change shape or properties upon exposure to specific stimuli, such as temperature or pH.[78] This dynamic capability is important for tissues undergoing continuous mechanical or biochemical changes, including cartilage or vascular grafts. Targeted cell placement further boosts the functionality of printed structures. For example, aspiration-assisted bioprinting enabled spheroid placement with an 11% margin relative to each spheroid's diameter, promoting scaffold-free bone growth.[79] Despite these advances, challenges persist. Vascularization of large printed constructs, ensuring regulatory compliance, and controlling print fidelity across different scales remain crucial priorities.[80] Cost and scalability issues also limit widespread clinical adoption. Still, as collaborative research integrates advanced bioink formulations, smart stimuli-responsive materials, and refined printing hardware, 3D and 4D printing stand poised to deliver transformative solutions for personalized tissue repair and regeneration.

Personalized formulations and bioinks

While 3D printing initially gained traction in manufacturing and surgical planning, its adaptation in tissue engineering and regenerative medicine has opened new avenues wherein pharmacists can play a pivotal role in optimizing therapeutic outcomes and ensuring patient

safety.[80] At the heart of 3D and 4D printing are bioinks, which are complex formulations typically composed of hydrogels, cells, and various bioactive components.[75] Pharmacists bring extensive expertise in compounding and formulation design, making them central to ensuring that the final scaffold or printed tissue is produced under stringent quality standards. For instance, novel hydrogels, including thermoresponsive polymers or composite materials doped with antibacterial agents, must be carefully characterized for stability, sterility, biocompatibility, and consistency.[81] In this context, pharmacists can contribute to selecting excipients or crosslinkers that minimize toxicity or immune responses, thereby advancing patient-specific treatments that integrate seamlessly into a patient's therapeutic regimen. Fig. 3 represents the impacts and applications of bioinks in the development of precision medicine.

This technology is necessary for the development of advanced cell-based products. The expanding scope of regenerative medicine involves the integration of stem cells, growth factors, and gene therapy components into printed constructs. Pharmacists are often responsible for handling biological products, adhering to best practices for storage, transport, and aseptic processing. As 3D-printed constructs become more "drug-like"— for example, incorporating biomolecules such as growth factors (BMP-4, VEGF) or antibiotics—pharmacists must collaborate with biomedical teams to evaluate dosing schedules, stability profiles, and interactions with other medications the patient may be taking.[79] Their skills in pharmacokinetics and pharmacodynamics will be vital in determining optimal release profiles that maximize regenerative outcomes while minimizing side effects.

Given that many 3D and 4D printed tissues and scaffolds involve living cells, these products align with biologics or advanced therapy medicinal products (ATMPs) categories.[80] Pharmacists, through their familiarity with good manufacturing practices (GMP) and regulatory frameworks (e.g., FDA, EMA), can guide product development to ensure compliance. This extends to validating the sterility and reproducibility of printed constructs, conducting risk assessments, and managing documentation. In addition, ongoing pharmacovigilance monitoring for adverse reactions post-implantation becomes a shared responsibility for clinicians and pharmacists, especially in the early commercialization stages of these new therapies.

Clinical and translational collaboration is another essential dimension in interprofessional approaches. Pharmacists, clinicians, biologists, bioengineers, and researchers must work closely to bring 3D- and 4D-printed therapies to patients. Pharmacists, with their deep understanding of formulations and drug-device combination products, can champion translational research that seeks to streamline the path from bench to bedside.[82] This includes designing stability studies,
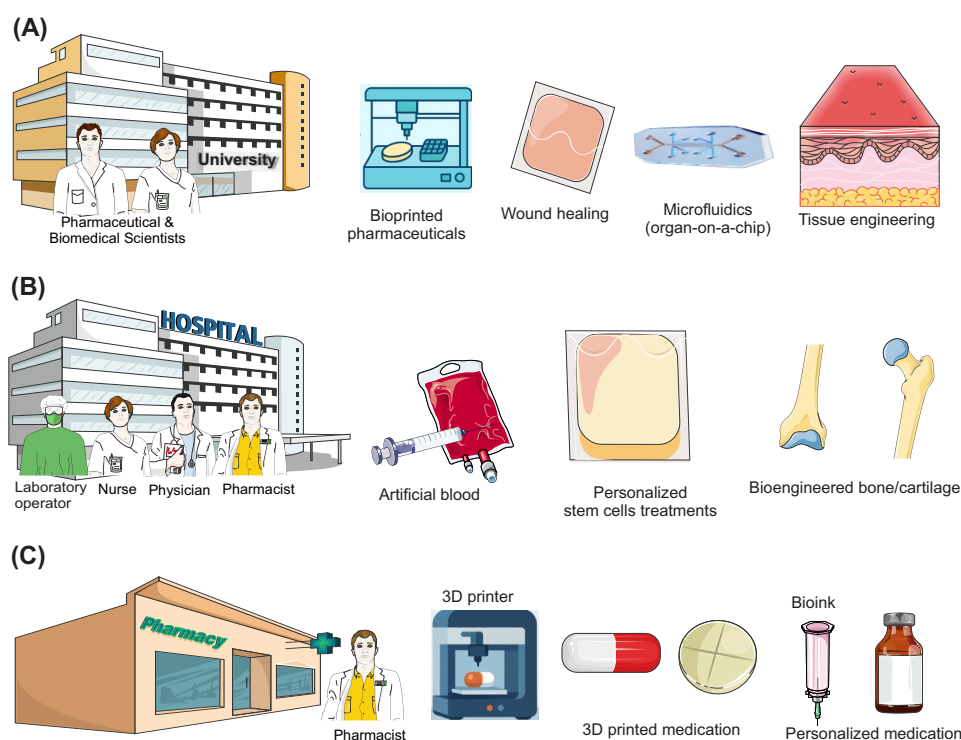

Fig. 3. Schematic illustration of the impacts and applications of advanced technologies (e.g., 3D prinitin, bioinks, etc) in the development of precision medicine. A) Universities and pharmaceutical industries initiate AI-assisted research and development of personalized medicine utilizing technolgies like microfluidics technology integrated with 3D printing using active pharmaceutical ingredients, excipients, and hydrogel incorporated with different entities. B) Major applications of bioinks in hospitals - a collaborative approach among medical doctors and pharmacists. (C) Futuristic pharmacy involved with new technologies such as 3D printing and bioinks for patient-specific services.

evaluating packaging, advising on cold-chain logistics for cell-laden formulations, and participating in multidisciplinary teams tasked with clinical trial design and execution. As these technologies mature, the pharmacy profession will likely see an expansion in roles such as "bioprinting pharmacists," who specialize in customizing bioinks and scaffolds in hospital-based or centralized compounding facilities. Strengthening educational curricula around biotechnology and additive manufacturing will thus be crucial. Additionally, ethical considerations, for instance, equitable access and long-term implant monitoring, will become central to practice guidelines, where pharmacists can offer leadership in policy-making and patient advocacy. Taken all, 3D and 4D printing technologies represent a transformative frontier for tissue regeneration and personalized healthcare. Pharmacists, recognized for their roles in formulation science, quality control, and patient-centric care, stand at the nexus of scientific discovery and clinical application. By leveraging their expertise, the pharmacy profession can drive safe, effective, and sustainable integration of these emerging regenerative therapies into standard healthcare practices.

Conclusion

Advancements in POCT and 3D printing are reshaping both the practice and education of pharmacists. POCT extends the scope of community and clinical pharmacy services by enabling swift, onsite diagnostic capabilities. Simultaneously, 3D printing introduces a novel dimension to pharmaceutical science, particularly in drug formulation and personalized medicine. The capacity to design and produce tailored dosage forms addresses individual patient needs such as dose specificity, ease of administration, and improved adherence. Nevertheless, harnessing this potential requires pharmacy education to incorporate laboratory instruction and interdisciplinary learning experiences, merging principles of pharmaceutics, engineering, and patient-centric care. With adequate institutional support, faculty training, and infrastructure, students can gain an experiential understanding of the entire 3D printing process, from conceptualization to quality assurance.

Overall, the successful adoption of POCT and 3D printing in pharmacy depends on strategic curriculum development, ongoing faculty development, and robust collaborations with external stakeholders such as healthcare institutions, policymakers, and industry partners. By embracing these emerging technologies and seamlessly integrating them into educational frameworks, the pharmacy profession is poised to assume an expanded role in primary and specialty care. This evolution not only benefits patient outcomes but also elevates the pharmacist's position as a dynamic healthcare provider, innovator, and integral member of multidisciplinary teams.

Review Highlights

What is the current knowledge?
- Point-of-care testing (POCT) systems have been marketed for monitoring of some diseases such as diabetes.
- 3D printing personalizes dosage forms, enhancing therapy in pharmacy practice.
- Various printing methods (FDM, SLS, Inkjet) are widely researched for drug development.
- Biodegradable polymers offer eco-friendly solutions and reduce toxicity risks.
- Regulatory frameworks for 3D printing in pharma are evolving but still lack clear guidelines.
- Pharmacists can use 3D printing to tailor pediatric, geriatric, and specialty treatments.

What is new here?
- Personalized POCT systems is a turnaround approach in controlling diseases by patients.
- The use of POCT as an early disease detection approach results in rapid intervention.
- The AI-driven design optimizes 3D-printed formulations for individualized patient needs.
- On-demand printing in pharmacies enables faster, personalized drug dispensing.
- Smart inhalers and implants can be custom-made via advanced 3D printing methods.
- SLA and multi-nozzle printers expand complex geometries for targeted drug release.
- Data-enriched tablets integrate dosing info and QR codes for safer medication use.
- Microfluidic-based bioprinting refines vascularization and nutrient flow in large tissue constructs.
- AI-driven slicing optimizes print paths, boosting efficiency, cell viability, and design complexity.

Authors' Contribution
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Methodology: Jaleh Barar, Yadollah Omidi.
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Competing Interests
The authors declare that they have no conflict of interest regarding this work.

Ethical Approval
None to be stated.

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