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A 3D-Printed Dosage Form Becomes Patient-Specific Only When Biopharmaceutics, Manufacturing Control, Prescribing Logic, and Dispensing Workflow Agree

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ABSTRACT

Three-dimensional printing can vary drug dose, geometry, composition, internal architecture, release characteristics, and patient-facing features with a degree of flexibility that conventional mass manufacture rarely provides. Yet technical customizability does not by itself establish that a resulting medicine is patient-specific. A clinically individualized product must retain a defensible relationship between the patient's therapeutic requirement and the attributes deliberately changed during manufacture. That relationship becomes vulnerable when dose modification alters release, when material or process variability changes product performance, when manufacturing instructions are detached from the authorized prescription, or when the dispensed unit cannot be linked reliably to its quality and production record. This Perspective examines patient specificity as a property of the complete manufacturing-use case rather than of printing technology alone. It distinguishes clinical specification, biopharmaceutical fitness, formulation and process control, release assurance, dispensing identity, and traceability as separate conditions that can succeed or fail independently. Clinical studies show that individualized printed medicines can be prepared and used in selected settings, but current evidence remains product-, technology-, and context-dependent. A defensible claim of patient specificity therefore requires more than a customized geometry or nominal dose: the intended therapeutic change must survive design, manufacture, verification, release, and dispensing without losing its clinical meaning.

Keywords: Pharmaceutical 3D printing, Personalized dosage forms, Biopharmaceutics, Additive manufacturing, Quality assurance, Point-of-care manufacturing

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Introduction

Pharmaceutical three-dimensional printing has progressed from a technological curiosity to a diverse family of manufacturing approaches capable of producing tablets, capsules, multipart systems, implants, films, and other dosage forms with digitally specified structures. Recent literature reflects a substantial expansion in materials, printing platforms, dosage-form concepts, and intended applications, together with increasing attention to translation beyond laboratory demonstration [1]. The same expansion has made the field harder to describe using a single idea of “3D printing,” because emerging solid-dosage technologies differ in material requirements,

thermal or photochemical exposure, process mechanics, critical quality attributes, and opportunities for in-process assessment [2].

The attraction of these technologies is closely connected to personalization. Digital design and relatively low-volume manufacture can, in principle, support changes in dose, geometry, release behavior, appearance, or formulation for smaller patient groups or individual patients. Policy and practice analyses have therefore begun to consider how pharmaceutical printing could intersect with pharmacy services, prescribing, governance, professional responsibility, and decentralized manufacture [3, 4]. These possibilities are scientifically important, but they create a terminology problem. A dosage form can be highly customizable from a manufacturing perspective while remaining only weakly connected to an individual patient's therapeutic requirements.

That distinction matters because the translational literature is considerably narrower than the experimental formulation literature. Reviews of clinical translation have documented promising examples while emphasizing the limited number of products and settings in which pharmaceutical printing has moved into real patient use [5]. Early-phase development analyses likewise position 3D printing as particularly attractive for rapid iteration, flexible batch sizes, and formulation exploration while acknowledging that established manufacturing platforms remain preferable for many conventional products and production scales [6]. The foundational manufacturing literature anticipated many of the design freedoms now being explored, but it did not eliminate the need for pharmaceutical controls simply because the manufacturing route is digital [7].

The central question is therefore not whether a printer can make two dosage forms different from one another. The more consequential question is which conditions must remain aligned for a particular manufactured unit to qualify as patient-specific in a clinically meaningful sense. This article examines that question across the clinical requirement that initiates customization, the biopharmaceutical consequences of changing a dosage form, the material and process controls needed to manufacture it reproducibly, the evidence needed to release individualized units, and the prescribing and dispensing information required to preserve identity and traceability. Patient specificity is treated here as a property of the linked manufacturing-use case. It is not assumed to follow automatically from the presence of a patient name, a modified computer-aided design file, or a nonstandard drug strength.

Patient specificity begins with an executable clinical requirement

A useful distinction begins before printing. Pharmaceutical customization acquires clinical meaning only when the characteristic being altered can be connected to a therapeutic or patient-use requirement. Real-world manipulation of prescribed medicines illustrates the underlying problem: patients and caregivers may divide, crush, disperse, combine, or otherwise modify available products because commercial presentations do not always match the required dose or mode of administration [8]. Such practices can identify unmet formulation needs, but they do not imply that every manipulated medicine should be replaced by an additively manufactured product. They instead show that manufacturing personalization should begin with a defined mismatch between the available medicine and the treatment requirement.

Pediatrics provides one of the clearest contexts in which this mismatch may arise. Dose requirements can change with body size, age, developmental stage, disease state, and therapeutic response, while dosage-form acceptability may depend on swallowing ability and other age-related factors [9]. Pharmaceutical 3D printing offers a potential way to manufacture smaller batches or patient-linked strengths without relying on repeated physical manipulation of conventional products. However, pediatric need cannot be reduced to “smaller dose.” A clinically executable specification may need to include strength, unit size, administration characteristics, release behavior, excipient suitability, and other product attributes relevant to the intended patient.

Direct clinical work demonstrates that such patient-linked manufacture is possible under selected conditions. Automated preparation of individualized isoleucine formulations has been evaluated prospectively in patients with maple syrup urine disease, providing an early example in which the manufactured formulation was connected to a defined therapeutic requirement [10, 11]. These studies are important because they move the argument beyond theoretical manufacturing flexibility. At the same time, rare-disease use in specialized clinical environments represents a narrow evidentiary base. It establishes feasibility for particular medicines and workflows, not a general rule that any digitally modified formulation is clinically individualized.

A second requirement is that the manufactured product must retain the intended pharmaceutical performance. A patient-specific dose is still a drug product, and its dose strength cannot be interpreted independently of the way

the dosage form releases and delivers the active substance. Clinical pharmacokinetic work comparing a point-of-care 3D-printed medicine with a conventional comparator demonstrates that printed products can be assessed using established bioequivalence principles when such comparison is appropriate [12]. The significance of that work extends beyond the specific product studied: a digitally specified dose does not make biopharmaceutical verification unnecessary.

Patient-facing customization adds another layer. Printed dosage forms can incorporate tactile or visual features, including Braille while maintaining a designed sustained-release function [13]. Such modifications may improve usability or accessibility for a particular patient group, yet an accessibility feature and a pharmacologically individualized dosage regimen are analytically distinct. One may be patient-relevant without changing systemic drug exposure; the other may directly affect therapeutic exposure. Both can contribute to patient specificity, but they do so through different clinical mechanisms.

Accordingly, a patient-specific dosage form is defined here as a released medicine whose selected characteristics are linked to an identifiable clinical requirement for the intended patient, whose necessary biopharmaceutical behavior is justified, whose manufacture remains within controlled material and process conditions, and whose prescription, release decision, and dispensing identity remain traceable to that patient. This definition does not require every attribute of a dosage form to be individualized. It requires the attributes that are changed to have a defensible clinical reason and to remain compatible with the intended therapeutic function.

Changing the printed object changes the biopharmaceutical problem

Once a patient-specific requirement is identified, manufacturing flexibility creates a second challenge: many of the variables that are easiest to change digitally are also variables capable of altering product performance. Printed capsule architectures have been used to support flexible dosing of cyclosporine-containing self-nanoemulsifying systems, demonstrating how a change in the physical product can accommodate a drug-specific formulation strategy [14]. Semi-solid extrusion has likewise been used to produce pectin-based simethicone gummies with flexible drug loading, illustrating how dosage-form type and dose can be adjusted together [15]. These examples show the breadth of customization, but each represents a particular formulation system whose manufacturing variables cannot be separated from its pharmaceutical behavior.

Geometry is especially important because it can operate simultaneously as a dose-setting variable and a release-controlling variable. In 3D-printed intravaginal rings, design and printing parameters can influence dimensions, structure, and drug-release behavior [16]. Multilayer capsule designs have similarly been explored as a means of constructing controlled-release profiles through spatial organization of the printed product [17]. In these systems, geometry is not merely cosmetic. Changing the digital design can change the path by which fluids enter the dosage form, the surface area available for dissolution, the location of drug-containing regions, and the sequence or duration of release.

Drug-specific therapeutic requirements can further increase the value of flexible manufacture. Benznidazole tablets produced using melting solidification printing have been investigated in the context of Chagas disease, where individualized dosing considerations create a practical rationale for flexible strengths [18]. The clinical justification originates from the treatment requirement; the printer provides one possible way to execute it. This order is important. A technically available range of printed strengths does not itself establish which strength is clinically appropriate.

The relationship between dose and release is therefore central to any claim of patient specificity. Experimental work has shown that 3D-printed oral dosage forms can be designed so that drug dose changes across a defined range while release behavior remains comparatively stable [19]. This is a powerful design objective because individualized dosing becomes safer to interpret when changing drug quantity does not unintentionally transform the release mechanism. The result should not be generalized beyond the tested formulation and design range, however. Dose independence is an engineered property, not a default consequence of printing.

Feedstock characteristics provide a complementary example. Work on printable emulsion gels has demonstrated that material attributes associated with printability are linked to the properties of the resulting tablets [20]. The implication is that a printer file alone does not fully specify the pharmaceutical product. The physical state and composition of the material entering the printer influence whether the intended geometry can be produced and whether the finished dosage form achieves its expected quality attributes.

For this reason, biopharmaceutical fitness is used here to mean sufficient evidence that the selected customization has preserved—or deliberately and appropriately changed—the drug-release and exposure-related function needed for the intended use. The term does not imply that every patient-specific formulation requires a formal bioequivalence study. It does mean that a change in dose, formulation, geometry, internal structure, release design, or manufacturing process should not be assumed pharmacologically neutral simply because the nominal amount of active ingredient is correct.

The practical relationships among customizable attributes, their clinical rationales, and the controls needed to preserve therapeutic meaning differ according to what is being changed.

Table 1. Patient-linked customization variables and the controls required to preserve therapeutic meaning

Customization request		**Product consequences and control**		**Patient-specific attribution**
Customized attribute	**Clinical reason for changing it**	**Biopharmaceutical consequence that must be considered**	**Manufacturing control required**	**Condition for calling the change patient-specific**
Drug amount per unit	Individualized dose requirement or unavailable commercial strength	Total delivered dose and, depending on design, dissolution or release behavior	Accurate material dosing, dimensional control, content uniformity and reproducible unit manufacture	The selected dose is clinically authorized and the manufactured unit reliably contains that intended amount
External geometry or unit size	Dose adjustment, administration needs, or patient handling considerations	Surface-area-to-volume ratio, disintegration, dissolution or release may change	Dimensional accuracy and validated relationship between geometry and product performance	Geometry is changed for a defined patient-linked purpose and its pharmaceutical consequences remain controlled
Internal architecture	Deliberate modification of release sequence or duration	Fluid penetration, diffusion path, erosion and release kinetics may change	Reproducible internal structure, layer placement, infill or equivalent process attributes	The architecture implements an intended therapeutic release behavior rather than an arbitrary digital variation
Formulation composition	Need to accommodate a specific drug, dose, process or patient-use constraint	Solubility, drug state, stability and release can change	Raw-material identity, composition, mixing and process compatibility	The formulation change is justified for the intended use and remains within a controlled pharmaceutical specification
Release-controlling design	Need for immediate, sustained, delayed or otherwise tailored delivery	Changes the time course of drug availability and potentially systemic exposure	Control of geometry, composition, structure and relevant release-critical variables	The requested release behavior is clinically justified and supported by appropriate product-performance evidence
Patient-facing dosage-form feature	Swallowing, handling, identification or accessibility need	May be neutral to exposure, but structural changes can still affect product performance	Reproducible feature formation without compromising dose or release	The feature addresses an identified patient need and does not undermine the therapeutic function of the dosage form
Multiple attributes changed together	Clinical requirement cannot be met by adjusting a single variable	Interacting changes may alter dose accuracy, dissolution, release or stability in non-additive ways	Multivariable design and control strategy capable of maintaining the combined product specification	The combined design is linked to the patient's requirement and each clinically relevant interaction remains controlled

The table makes visible a recurring distinction: personalization can originate in different product variables, but the evidentiary burden depends on the pharmaceutical consequence of changing that variable. A visually obvious

alteration may have little effect on exposure, whereas a small structural or formulation change may materially alter release. Patient specificity therefore cannot be inferred from the magnitude of visible customization.

Manufacturing flexibility is bounded by material and process control

The capacity to generate many digital designs is meaningful only if those designs can be converted into reproducible pharmaceutical products. Different printing platforms impose different material constraints. Systematic screening of photopolymer resins for stereolithographic manufacture has shown that formulation factors strongly influence printability and the characteristics of the resulting solid dosage forms [21]. A design that is geometrically feasible in software may therefore be impractical with the selected material system or may require formulation changes that alter the pharmaceutical product itself.

Quality-by-design approaches provide one route for defining these relationships before routine manufacture. Fused-deposition modeling has been examined using QbD methodology to identify combinations of formulation and process variables capable of producing immediate-release tablets with predefined performance characteristics [22]. The important principle is not that one design space can be transferred unchanged to another product. The value of QbD lies in making explicit which material attributes and processing conditions influence the critical qualities of a particular printed medicine.

Multivariable experiments reinforce this point. Factorial evaluation of fused-deposition modeling has demonstrated that several customization and process variables can interact in determining the characteristics of printed medicines [23]. Such interactions challenge the intuitive assumption that digital parameters can be adjusted one at a time while the rest of the product remains unchanged. A change introduced to deliver a different dose may also affect geometry, mass, surface area, thermal history, mechanical properties, or dissolution. The clinically desired alteration and the manufacturing response must therefore be evaluated as a coupled system.

Alternative printing routes may reduce some process burdens while introducing others. Temperature-facilitated direct extrusion, for example, can bypass a separate filament-manufacturing stage and thereby simplify the path from powder or blend to printed dosage form [24]. Process simplification can be valuable for small-batch or decentralized manufacture, but removing one manufacturing step does not remove the need to characterize material behavior, process limits, product consistency, and stability. The control strategy changes with the process.

The lifecycle of the feedstock is equally relevant. Fused-deposition-manufacturing filaments have been investigated as potential shelf items for later on-demand tablet production, with stability assessed over storage [25]. This question becomes especially important in patient-specific manufacture because on-demand production may depend on maintaining qualified intermediate materials for periods during which no printing occurs. A printer operating within its nominal settings cannot compensate for a feedstock that has changed outside the material state on which the process was established.

Digital connectivity adds another layer of flexibility. Smartphone-enabled pharmaceutical printing has demonstrated that manufacture can be controlled through portable digital interfaces, illustrating how product instructions might be transferred and executed across increasingly decentralized environments [26]. Such technical connectivity is potentially useful for distributed manufacture, but it also clarifies the difference between a digital manufacturing instruction and a clinically authorized prescription. A printable file can specify geometry and process commands; it does not, by itself, establish that the resulting product is appropriate for a particular patient.

Hospital-based formulation work provides a practical test of these boundaries. Development of direct-powder-extrusion formulations for hospital printing has shown that suitable excipient systems can support immediate-release manufacture while also revealing drug- and formulation-specific compatibility problems [27]. This is precisely the type of negative or conditional evidence required for a realistic account of personalization. The existence of a pharmaceutical printer in a hospital does not make arbitrary active ingredients interchangeable manufacturing inputs. Each intended product still confronts material compatibility, processing, stability, and performance constraints.

Manufacturing flexibility should therefore be understood as a controlled capacity to produce predefined variation, not as permission for unrestricted modification. A patient-specific production system must know which changes are clinically intended, which manufacturing variables are allowed to move with them, which variables must remain constrained, and what evidence establishes that the resulting product still satisfies its pharmaceutical specification. This requirement becomes more demanding as batch size decreases, because conventional

assumptions about large-batch sampling and release become less useful when every unit or small series may represent a different prescription.

The next question is consequently one of release evidence: how can an individualized product be verified without treating every printed unit as if conventional batch-manufacturing logic still applied unchanged?

Individualized units require release evidence at individualized scale

As production moves from conventional batches toward small series or individual units, quality assurance must follow the scale at which meaningful variation is introduced. Non-destructive analytical approaches are therefore particularly relevant to pharmaceutical 3D printing because they can interrogate finished units without consuming the product intended for dispensing [28]. Their value is greatest when printing parameters, geometry, or dose may differ between prescriptions and when conventional batch-level assumptions no longer describe every manufactured unit adequately.

Near-infrared spectroscopy has been incorporated as process analytical technology during point-of-care printing, demonstrating that product attributes can be estimated while manufacture is occurring [29]. Earlier work also showed rapid non-destructive dose verification of printed medicines using spectroscopic measurements linked to reference analytical data [30]. More recently, real-time monitoring during selective laser sintering has been investigated for lamivudine content quantification [31]. Together, these studies establish analytical feasibility, not a universal release method. Calibration remains dependent on the product, material system, process, concentration range, and reference method.

For patient-specific manufacture, the important distinction is between measurement and release authorization. A spectral or process model may provide evidence about identity, content, or another attribute, but the decision that a product is suitable for dispensing still depends on a defined specification and a validated relationship between the measurement and the relevant quality attribute. Individualized manufacture therefore strengthens the case for rapid, non-destructive and potentially in-process assurance while simultaneously increasing the importance of product-specific analytical validity.

Prescription intent must survive manufacture, release and dispensing

A clinically individualized medicine begins as a therapeutic decision, whereas a printer executes manufacturing instructions. These are related information objects but they are not interchangeable. The prescription specifies what treatment is authorized for the patient; the manufacturing specification must translate the relevant elements of that decision into formulation, dose, geometry, process, and release requirements. Digital control can make this translation technically efficient [26], but technical transfer does not establish that the clinical decision has been interpreted correctly.

This distinction becomes more important in decentralized settings. Reviews of pharmaceutical 3D printing in hospitals and pharmacies describe a small but growing set of practical applications while emphasizing unresolved requirements involving equipment, materials, personnel, quality control, regulation, and workflow [32]. Broader analyses have long anticipated a route from digitally enabled drug development toward flexible frontline manufacture [33], yet an end-to-end clinical pathway remains substantially less established than the technologies used at individual stages.

A patient-specific product therefore requires traceability across the handoffs that connect prescribing to dispensing. The clinically intended dose and product characteristics must be translated into an executable specification; the correct material and process state must be used; release evidence must correspond to the manufactured product; and the dispensed unit must remain linked to its prescription and production record.

The resulting allocation of responsibilities is not simply a sequence of technical tasks; each handoff preserves a different part of the product's patient-specific identity.

Table 2. Information and responsibility handoffs required to preserve patient-specific identity

Workflow function	Information that must be preserved	Operational responsibility	Required handoff	Traceability record	Failure consequence
Clinical authorization — Prescribing	Patient, medicine, dose, regimen, clinically required	Authorize the treatment requirement	Convert clinical intent into a complete manufacturing	Authorized prescription and patient-	Printed product may be customized without being clinically justified

	product characteristics		request without adding unsupported assumptions	linked specification	
Formulation and manufacturing execution					
Formulation/manufacturing preparation	Composition, material state, design parameters and approved process conditions	Translate the prescription specification into a manufacturable product	Confirm that requested characteristics are feasible within the qualified formulation/process domain	Controlled formulation and digital manufacturing record	Correct clinical request may be converted into an unsuitable or nonreproducible product
Printing/manufacture	Approved digital design, material identity, machine settings and process state	Produce the intended unit reproducibly	Maintain correspondence between the authorized specification and actual manufacturing execution	Unit or batch manufacturing record	The printed unit may differ from the product that was authorized
Release and patient delivery					
Quality control/release	Attributes that establish identity, dose, performance and other required quality characteristics	Determine whether the manufactured unit satisfies its release specification	Link analytical evidence to the exact manufactured product	Release decision with associated analytical record	Technically completed printing may be mistaken for acceptable product quality
Dispensing	Patient identity, prescription, released product identity, directions and relevant product-specific information	Supply the correct released medicine to the intended patient	Match the released product instance to the active prescription	Dispensing record linked to product identity	Quality-assured product may lose patient specificity through misidentification or substitution
Post-use evidence loop — Patient/use feedback	Administration experience, usability and clinically relevant response where collected	Return meaningful information to the care pathway	Associate feedback with the actual formulation and product version used	Patient/product-linked follow-up record	Outcomes cannot be interpreted reliably if product version and use history are disconnected

These interfaces can be represented as four interacting domains rather than as a single manufacturing chain. The product instance becomes attributable to one patient only when clinically necessary information survives all relevant interfaces.

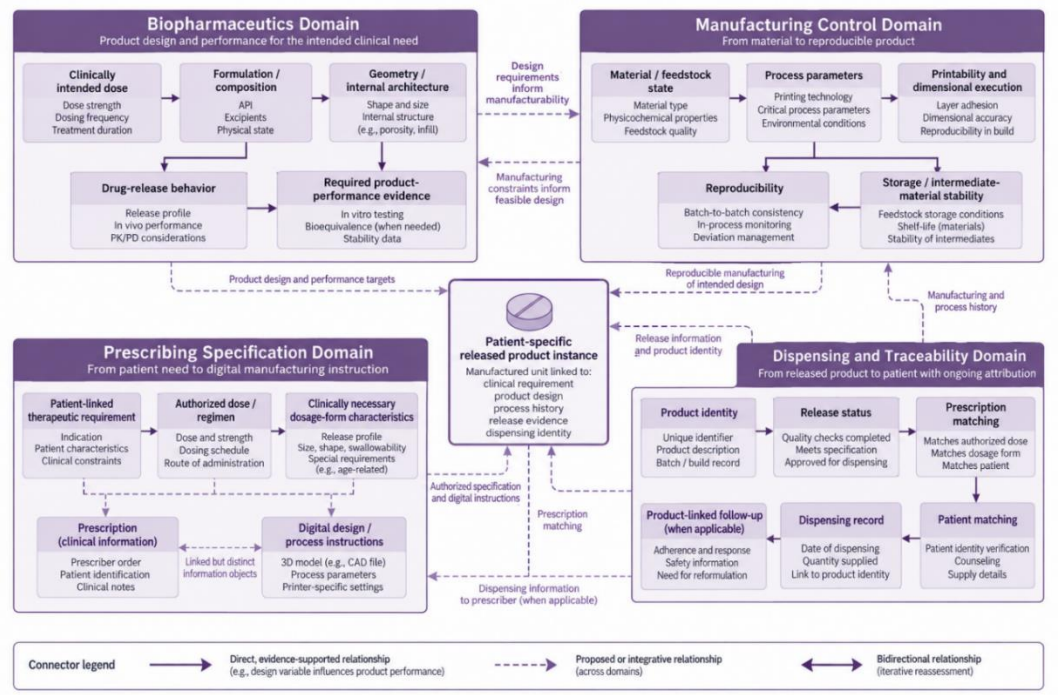

Figure 1. Clinical attribution of a patient-specific printed product depends on four interacting domains

Where personalization fails despite successful printing

A dosage form can be manufactured exactly as designed and still fail the operational definition of patient specificity. The most obvious case occurs when the design is changed without a patient-linked clinical requirement. A second occurs when the nominal dose is individualized but the modification unintentionally alters release or exposure. A third arises when an appropriate design cannot be manufactured reproducibly within the qualified material and process domain. A fourth appears when analytical evidence is insufficient to establish that the manufactured unit satisfies its specification. A fifth occurs downstream, when a released product cannot be linked reliably to the prescription and patient for whom it was made.

These failure modes are independent enough that success at one stage cannot compensate automatically for failure at another. The distinction also accommodates a counterexample important to the central thesis: individualized therapy may sometimes be delivered perfectly well using an existing standardized product. Patient-specific care therefore does not inherently require patient-specific manufacture.

Table 3. Technically successful printing scenarios that still fail to establish patient specificity

Observed configuration		Attribution break		Recovery condition
Scenario	**What technically succeeds**	**Missing patient-specific link**	**Why the claim fails**	**What would be needed to restore the claim**
Arbitrary geometric customization	Intended geometry prints correctly	No clinical reason for the change	Manufacturing variation is not linked to therapeutic need	Defined patient requirement and justified product attribute
Correct nominal dose with altered release	Printed unit contains the requested drug amount	Intended exposure behavior is not preserved or justified	Dose alone does not define pharmaceutical equivalence	Product-performance evidence appropriate to the changed design
Valid prescription but uncontrolled process	Clinical requirement is appropriate	Manufacture is outside established material/process conditions	The intended product cannot be assumed reproducible	Controlled manufacturing domain and evidence of reproducibility

Successful printing without adequate release evidence	Unit appears physically acceptable	Quality status is unresolved	Completion of printing is not a release decision	Valid analytical evidence linked to the product specification
Released unit with broken identity chain	Product passes quality assessment	Patient/prescription/product linkage is lost	The released medicine is no longer demonstrably the intended patient's product	End-to-end product, prescription and dispensing traceability
Individualized therapy using a standard product	Clinical treatment is appropriately personalized	No customized manufacture is necessary	This is not a failure of care; it disproves any claim that personalization requires printing	No manufacturing customization needed when the standard product already meets the requirement

The same logic can be expressed as a design-to-use information thread in which clinical, manufacturing, analytical, regulatory, and dispensing functions remain distinguishable.

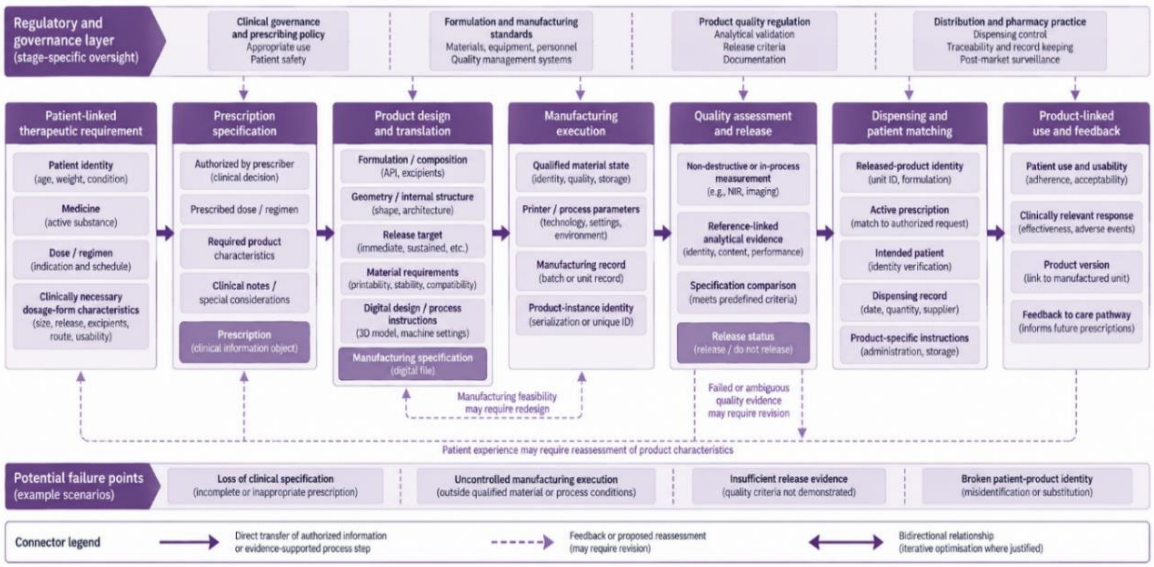

Figure 2. The patient-specific design thread can fail at distinct scientific and operational interfaces

Results and Discussion

The evidence supports a narrower interpretation of pharmaceutical personalization than manufacturing flexibility alone would suggest. Clinical studies demonstrate that patient-linked printing can be achieved in selected medicines and specialized settings [10]. Product-specific pharmacokinetic work further shows that printed formulations can be tested against conventional biopharmaceutical expectations where appropriate [12]. The broader translational literature, however, continues to show a gap between experimental customizability and routine clinical implementation [5].

This gap is understandable because each additional degree of manufacturing freedom creates another variable whose pharmaceutical meaning may need to be established. Multivariable process studies demonstrate that printed-product attributes arise from interacting formulation and process conditions [23]. Analytical studies likewise show that rapid or real-time quality assessment is technically feasible while remaining dependent on product-specific calibration and validation [29]. These findings argue against interpreting digital design as an autonomous layer that can be separated from pharmaceutical development.

The practical research priority is therefore to test the interfaces between established technical capabilities. Studies should determine when a clinically requested change can be translated reproducibly into a manufacturing specification, when changes in geometry or composition require new biopharmaceutical evidence, how analytical models can be transferred or revalidated across individualized variants, and how product identity is preserved

through dispensing. Demonstrations that integrate these functions prospectively are more informative for clinical translation than additional examples showing only that another shape, dose, or formulation can be printed.

The same reasoning limits claims about point-of-care manufacture. Hospital and pharmacy applications remain comparatively few [32]. Their expansion will depend on product-specific scientific evidence together with workable responsibilities for prescribing, production, quality release, documentation, and dispensing. A credible patient-specific use case therefore emerges from coordination among these functions rather than from the location of the printer itself.

Conclusion

Three-dimensional printing can provide an unusually flexible means of changing pharmaceutical dose, formulation, geometry, internal architecture, release behavior, and patient-facing features. Those capabilities make patient-specific manufacture possible, but they do not make every customized product patient-specific.

The stronger claim is conditional. A printed medicine becomes patient-specific when the characteristic being changed answers an identifiable clinical requirement; the resulting formulation remains biopharmaceutically appropriate; material and process conditions can reproduce the intended product; release evidence applies to the actual manufactured unit; and prescription, product identity, release status, and dispensing remain traceably connected to the intended patient. Failure at any of these interfaces can leave a technically successful print clinically nonspecific. Conversely, when an existing standardized medicine already satisfies an individual's requirement, personalized care does not require personalized manufacture.

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