

Technology Transfer of Photopolymer Manufacturing to Contract Manufacturers: Knowledge Packages, Training, Capability Evidence and Change Control

A bounded engineering framework for moving a controlled photopolymer manufacturing state to an external receiving site

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Abstract

Technology transfer to a contract manufacturer is not a document handoff. For photopolymer manufacturing it is the controlled transfer of a manufacturing state: material definitions, equipment and facility conditions, process knowledge, quality evidence, training needed to reproduce the transferred process, and the change-control rules that preserve that state after handover. The evidence base used here contains no peer-reviewed journal article. It combines one photopolymer-specific NIST technical report, additive-manufacturing site and equipment controls, pharmaceutical technology-transfer guidance used only for governance architecture, and four vendor, commercial or contractual documents used only as named existence cases [1-9]. No direct empirical end-to-end study of photopolymer-manufacturing transfer to a contract manufacturer was located in the evidence base assembled for this review.

Accordingly, ER-479 presents an engineering synthesis rather than a validated universal protocol. The framework separates the sending unit from the receiving unit, defines the transfer package, treats training only as a transfer deliverable, requires capability evidence tied to the receiving process state, and retains formal change control after handover. It does not prescribe universal sample counts, acceptance thresholds, requalification intervals, transfer durations, capability targets, batch counts, document counts or lead times. A proposed difference register and handover exercise connect receiving-site evidence to the exact state and conditions transferred.

Keywords: photopolymer manufacturing; technology transfer; contract manufacturing; knowledge transfer; receiving site; capability evidence; change control; additive manufacturing

1. Significance and scope

Photopolymer additive manufacturing is moving from development activity toward scalable industrial manufacturing, which increases the importance of reproducibility, standardisation, testing, training, shared data infrastructure and collaboration across organisations [1]. A transfer to an external manufacturer adds a further problem: a process that is controlled at the sending site must be reproduced at a receiving site without assuming that the same machine label, resin name or work instruction creates the same manufacturing state.

The purpose of ER-479 is therefore to define what must be transferred, demonstrated and governed when photopolymer manufacturing is handed to a contract manufacturer. It addresses the one-to-one transfer project: the sending package, receiving-site readiness, transfer-specific training, evidence of reproduced capability and post-handover change control.

1.1 Corpus boundary

ER-479 owns the sending-to-receiving transfer package, external manufacturer readiness, transferred process knowledge, evidence that the receiving site can reproduce the controlled photopolymer manufacturing state, and change control after handover. ER-480 retains the internal personnel competence architecture outside a specific transfer project. ER-476 retains distributed or regional manufacturing equivalence as a network architecture. ER-489 retains chain-of-custody verification for distributed manufacturing. References to those neighbouring topics are boundary statements only.

2. Evidence architecture and transfer limits

The evidence join is deliberately bounded. The NIST photopolymer workshop report supports the need for reproducible and scalable PAM, standardisation, testing, workforce development and industrial collaboration, but it does not prescribe contract-manufacturer transfer [1]. ISO/ASTM 52920 supports production-site qualification logic at abstract level and is material- and method-independent rather than a transfer method [2]. NASA-STD-6033 provides aerospace AM controls for facilities, equipment, feedstock, configuration and training, including liquid feedstock, but those requirements are not presented here as universally mandatory outside their scope [3].

WHO technology-transfer guidance and ICH Q10 provide a sending-unit/receiving-unit architecture, documented knowledge transfer, qualification or validation governance, knowledge management and lifecycle change management [5,6]. They are pharmaceutical sources and are used only for generic transfer-governance architecture; this review does not imply that pharmaceutical GMP requirements apply to general photopolymer manufacturing. JPL QC131, 3D Systems service material, a named SLA contract manufacturer and a named VPP contract manufacturer establish only that external or subcontract AM control arrangements exist in named contexts [4,7-9]. They do not establish sufficiency, universality, photopolymer equivalence or a complete transfer method.

Table 1. Transfer-package layers and the evidence boundary applied in ER-479.

Transfer layer	Engineering purpose	Evidence boundary
Controlled process definition	State what is being transferred: materials, equipment state, workflow, quality endpoints and configuration.	PAM context from NIST; site/control logic from AM sources [1-3].
Knowledge package	Carry the process rationale, controlled instructions, data and decision records needed by the receiving site.	Governance architecture from WHO/ICH; vendor material is existence-case support only [5-7].
Transfer-specific training	Enable the receiving team to execute the transferred process and recognise its controlled state.	Training is a project deliverable, not an internal competence system [3,5,7].
Capability evidence	Show that the receiving site can reproduce the intended controlled state and delivered result.	No universal threshold is inferred; evidence must remain process- and site-specific [2-4].
Handover and change control	Preserve the transferred state after release and route future changes through controlled evaluation.	Lifecycle/change-governance logic from ICH plus AM configuration-control logic [3,6].

3. Define the controlled state before transfer

A transfer project should begin by defining the process state that the receiving site is expected to reproduce. For photopolymer manufacturing this includes the material identity and feedstock state, equipment and facility conditions that can influence processing, the controlled workflow, the quality endpoints that define acceptable manufacture, and the configuration information needed to distinguish a validated state from a changed one. NIST identifies reproducibility, standardisation and measurement as central industrialisation needs for PAM [1]. ISO/ASTM 52920 and NASA-STD-6033 reinforce the need to control the production site, equipment, feedstock and process configuration, although they do so in broader AM and aerospace contexts [2,3].

The sending unit should therefore transfer the process as a state definition rather than as a recipe detached from context. The framework does not assume that identical nominal hardware or material labels make sites equivalent. The receiving site has to demonstrate that the variables that matter to the intended manufacturing claim remain controlled in its own environment.

4. Build a knowledge package that explains the process

Formal technology-transfer guidance separates the responsibilities of the sending and receiving units and treats documentation, process knowledge, data and qualification evidence as transfer objects rather than as incidental records [5]. ICH Q10 likewise places product and process knowledge, control strategy, validation approach and knowledge management within lifecycle transfer and change management [6]. ER-479 adopts that architecture without importing pharmaceutical regulatory obligations into general photopolymer manufacture.

A photopolymer transfer package should therefore make the controlled process intelligible to the receiving manufacturer. It should identify what is fixed, what may be adjusted, what evidence established the current state, what failure modes are known, what records must be returned to support release, and what changes cannot be made without review. The exact document set is project-specific; no universal document count or template is prescribed. Vendor technology-transfer material demonstrates that gap assessment, validation documentation, process controls and workflow handover are offered in industrial AM practice, but this is an existence case rather than independent proof of a sufficient package [7].

5. Receiving-site readiness is more than equipment availability

The receiving site must show that it can execute the transferred process under controlled conditions. ISO/ASTM 52920 supports production-site qualification logic, while NASA-STD-6033 provides a more detailed aerospace example of facility, equipment, feedstock, configuration and operator controls [2,3]. JPL QC131 provides a named subcontract AM case in which supplier requirements include material traceability and specified deliverables [4]. The JPL clause is an existence case in its own contractual and process context; it is not a universal PAM transfer standard.

Readiness evidence should therefore be tied to the receiving site and the process being transferred. It can include confirmation of material control, equipment state, environmental or workflow controls where relevant, calibrated or verified measurement capability, controlled software or build configuration, and the ability to generate the records on which the sending organisation will base acceptance. The framework intentionally does not prescribe universal acceptance thresholds or capability indices.

6. Training is a transfer deliverable

Training in ER-479 exists only to enable the receiving organisation to reproduce the transferred manufacturing state. NASA-STD-6033 includes operator training within equipment and facility control, WHO transfer guidance includes trained personnel within the receiving function, and 3D Systems describes technology-transfer services that include workflow and know-how handover [3,5,7]. These sources support the existence and relevance of transfer-specific training, not a universal internal competence architecture.

The transfer project should therefore identify the knowledge and practical actions that must be demonstrated before the receiving site operates independently. That may include recognising the controlled material state, executing the manufacturing workflow, responding to deviations, maintaining traceable records and knowing when a change requires escalation. Ongoing role architecture, general personnel development and competence governance outside the transfer project remain outside ER-479.

7. Capability evidence must close the transfer loop

A transfer is not complete merely because information has been delivered. The receiving site must generate evidence that the transferred process can be reproduced in its own controlled state. The evidence should connect receiving-site inputs and configuration to process response and delivered manufacturing outcomes. ISO/ASTM 52920 supports this site-qualification logic at a generic AM level, while NASA-STD-6033 shows how equipment, feedstock and configuration controls can be made explicit in a high-consequence AM environment [2,3].

ER-479 does not define a universal statistical acceptance plan. The depth of capability evidence depends on the process claim, the degree of site difference, the consequence of failure and the variables that can alter the manufactured result. What matters is traceability: the

receiving evidence must be sufficient to show that the process being accepted is the process that was intended to be transferred, not simply a locally successful build.

8. Handover does not end change control

Technology transfer creates a new controlled baseline at the receiving site. ICH Q10 treats knowledge management and change management as lifecycle activities, while NASA-STD-6033 provides AM-specific configuration-control logic in its own aerospace scope [3,6]. ER-479 uses those principles to require a defined route for changes after handover, without importing pharmaceutical or aerospace requirements as universal rules.

A post-handover change should be assessed against the transferred state: material, equipment, software or build configuration, facility conditions, workflow, measurement method, post-processing or another controlled variable relevant to the specific process. The response can range from documented review to additional evidence or re-transfer of affected knowledge, but ER-479 does not prescribe universal change categories, intervals or automatic requalification rules.

9. Named external-manufacturing cases: existence, not proof

The source base contains named examples showing that external or contract AM manufacturing arrangements exist. JPL publishes supplier requirements for subcontract AM in its contractual context [4]. 3D Systems markets technology-transfer services for in-house or third-party AM manufacturing [7]. A named contract manufacturer is reported by 3D Systems as using SLA production for industrial and healthcare customers [8], and Sinto Advanced Ceramics advertises industrial VPP contract manufacturing and series-production capability [9].

These four documents are vendor, commercial or contractual sources and are used only as existence cases. They do not show that a particular technology-transfer package is sufficient, do not establish photopolymer process equivalence, and do not validate a universal control architecture. Their role in ER-479 is to demonstrate that the external-manufacturing setting addressed by the framework is real, not to supply the framework itself.

10. Use a difference register to define the transfer experiment

The proposed transfer register compares the sending and receiving states before deciding which evidence can be reused. Each row identifies a relevant difference, its plausible route to a changed result, the observation needed to investigate that route and the person responsible for disposition. A difference may concern measurement capability or workflow as well as the printer itself. The register should avoid treating every difference as equally important or assuming that an unlisted difference is irrelevant.

Consider a hypothetical transfer in which the same material and printer model are used but the receiving site has a different post-cure fixture. The engineering question is whether the fixture change alters the state relevant to the delivered claim. Matching nominal exposure time would not answer that question by itself. The transfer programme would identify the affected observables and compare representative output under the declared configurations. This is a study-design example, not a conclusion about any fixture.

The receiving site should generate its own traceable records. Copying the sending site's successful result into the transfer package would document the source capability but would not demonstrate reproduction at the receiving site.

11. Make handover conditional on closure of defined differences

A proposed handover record would state which differences were accepted on existing evidence, which required new evidence and which remain outside the transferred scope. Conditional acceptance should name its conditions. It should not create an apparent unrestricted capability when the demonstration covered only one geometry, material family or post-processing arrangement.

A useful transfer trial can include a deliberately selected deviation scenario to test recognition and escalation. The objective would be to observe whether the receiving organisation preserves the controlled process and its decision records when routine conditions are interrupted. Such an exercise is proposed here as a governance test, not as an externally required validation step.

After handover, changes should be evaluated against the receiving baseline and the rationale that supported it. If a later change invalidates a critical transfer assumption, the relevant evidence and knowledge transfer must be revisited. Measuring transfer success solely by the first accepted build would omit this persistence question. A stronger empirical study would report the initial demonstration, deviations encountered and the behaviour of the control system after subsequent changes.

12. Capability-transfer evidence and acceptance logic

Technology transfer should be assessed as a comparison of controlled manufacturing states, not as confirmation that documents were transmitted. The receiving site must be able to reproduce the required product attributes within agreed limits, using its own machines, operators, environment and material logistics. Differences that appear inconsequential on paper, such as optical output calibration, wash loading or resin conditioning, may nevertheless affect the final material state and therefore require a documented assessment.

A proposed transfer experiment should distinguish setup qualification from routine capability. Equipment and software records establish installation and configuration; a challenge build tests identified edge-of-window risks; repeated lots then provide evidence of within-site reproducibility. Transfer acceptance should depend on predefined product-specific requirements and measurement reliability, not on unqualified pass/fail counts. Statistically limited evidence must be labelled provisional.

Deviations are most informative when the sending and receiving sites use a common classification and share raw measurement methods. Each difference should be linked to a potential process mechanism, a testable mitigation and an accountable decision

maker. The resulting acceptance ledger would include closure evidence, residual limitations, training status and triggers for renewed qualification after changes to resin source, optics, post-cure or final inspection.

The transfer package does not demonstrate that any particular contractor meets the requirements. ISO/ASTM 52920 and the documented quality-system sources provide general architecture; specific acceptance margins must be developed for the actual product and its intended use.

The evidence join is explicit: photopolymer industrialisation context from NIST, generic and aerospace AM control logic, pharmaceutical transfer-governance principles used only by analogy, and named external-manufacturing existence cases. With no direct empirical end-to-end PAM contract-manufacturer transfer study located, ER-479 remains an engineering framework rather than a validated universal protocol.

Knowledge transfer is not the transfer of a recipe alone

A transfer package needs to explain which outcome is required, which settings are merely implementation choices, and which deviations can change material state. For vat photopolymerisation this includes exposure-field characterisation, orientation and support logic, green-part handling, washing endpoint, post-cure conditions, environmental controls and acceptance testing. Capturing a successful build file without these dependencies can produce apparent repetition with changed chemistry or mechanics. The recipient should be able to identify critical process parameters, verify measurement systems and reconstruct the state of each accepted lot, rather than only reproduce a nominal print time.

Demonstrating receiving-site capability

The sending site can provide reference results, but a receiving site must demonstrate its own ability to meet defined requirements. A structured exercise should include independent runs, routine operators, representative geometries and pre-specified acceptance criteria. Transfer success cannot be declared from a single visually acceptable part. Comparisons should distinguish systematic bias, run-to-run variation and the influence of measurement uncertainty. Where the two sites use different exposure systems, wash stations or post-cure equipment, the change should trigger a bridging study rather than an assumption that equal nominal settings represent equal delivered treatment.

Boundary of guidance used in the review

Pharmaceutical quality-system and general additive-manufacturing guidance may offer valuable concepts of knowledge management, change control and deviation handling, but their scope must not be silently transferred to every photopolymer product. A medical-device application may carry additional legal duties absent from a prototype or industrial tooling application. The review consequently proposes a graded qualification logic: record intended use and critical-to-quality characteristics first, then justify which transfer controls are proportionate. References drawn from other industries support the method of governance, not product-specific validation data.

Transfer acceptance must test reproducibility, not document completeness

A technology-transfer package can contain a complete formulation recipe and still fail when transferred. Critical differences can reside in mixing order, equipment shear and heat transfer, local environmental conditions, metrology, light-source spectrum, washing or post-cure exposure. The receiving site should therefore perform staged demonstration runs against agreed performance characteristics, with documented material lineage, training records, deviations and the disposition of failed lots. A reference run at the transferring site provides a comparison baseline but not automatic equivalence.

Changes arising after transfer should be screened for effect on the qualified material-process state and escalated according to predefined change categories. In particular, a different photoinitiator supplier, wash solvent or curing apparatus may alter the final material state without changing nominal product nomenclature. Lessons from general quality-system guidance support a controlled transfer protocol, but do not substantiate numerical photopolymer acceptance limits absent targeted experimental evidence. This distinction is essential when the receiving site uses contract manufacturing and the intellectual-property disclosure must remain bounded.

Transferring capability, not merely documentation

A complete master recipe does not establish that a receiving contract manufacturer can reproduce an accepted output. Each specified material, exposure condition, finishing step and inspection rule must be linked to evidence generated on the receiving site. Transfer readiness is thus a demonstration of capability under defined conditions, not a document handover milestone.

A difference register should distinguish controlled deviations from unresolved mismatches. For each difference, define affected quality attributes, available tests, decision authority and acceptance evidence. Where the sending and receiving sites employ non-

identical equipment, parameter matching by nominal setting is insufficient: the actual output of the exposure and post-processing chain must be assessed. Changes should be approved for a bounded product family rather than treated as globally transferable.

Acceptance should include failed or marginal test cases and a traceable method for escalation, because training records alone cannot reveal process instability. The review should avoid presenting a proposed minimum transfer dossier as a published consensus standard unless each element is independently supported.

13. Limitations and research priorities

The evidence base has important limitations. It contains no peer-reviewed journal article and only one source whose declared direct domain is photopolymer additive manufacturing [1]. The strongest governance sources are pharmaceutical [5,6]; the detailed AM control sources are generic or aerospace [2-4]; and the external-manufacturing examples are existence cases [4,7-9]. No direct empirical end-to-end study was located that follows a photopolymer manufacturing process from a sending organisation through transfer to a contract manufacturer and then demonstrates reproduced capability under controlled change management.

Future work should report the transferred process state, relevant differences between sending and receiving sites, transfer-specific training and capability evidence, deviations encountered, and how later changes were controlled. Such studies would allow this framework to be tested rather than merely bounded.

14. Conclusions

Technology transfer of photopolymer manufacturing to a contract manufacturer should be treated as transfer of a controlled manufacturing state, not as shipment of files or equipment. The sending organisation defines the state and the evidence behind it. The receiving organisation demonstrates readiness, receives the knowledge needed to reproduce the process, completes transfer-specific training, and generates capability evidence tied to its own controlled conditions. Handover establishes a receiving-site baseline that remains subject to change control.

Competing interests

The author is Founder, CEO and CTO of 3Dresyns by Resyner Technologies S.L. The company develops and supplies photoresins and related process materials. No proprietary formulation, manufacturing sequence, process window or comparative product recommendation is disclosed.

Data availability

No new experimental datasets were generated for this review.

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