Each ledger entry stored by the audit engine contains the fields:

(i) Unique cartridge identifier --> §11.10(a) user tracking

(ii) Sensor value and dose volume --> §11.50(a) data integrity

(iii) SHA-256 hash --> §11.10(e) tamper evidence

(iv) Ledger block timestamp --> §11.30(d) time-stamped record

Together these satisfy the predicate rule requirements for electronic batch records in biopharmaceutical production.

Method claims

1. (Independent — deterministic core) A computer-implemented method for adaptive intervention in an industrial process, comprising: (a) authenticating a replaceable intervention cartridge by reading a unique machine-readable identifier stored in non-volatile memory, the cartridge housing (i) at least one in-line sensor, (ii) a reservoir containing an intervention agent, and (iii) an electronically controlled micro-pump fluidically coupled to the reservoir; (b) acquiring, in real time, at least one process-parameter value from the sensor; (c) comparing the process-parameter value with a stored threshold that is fixed a priori in memory; (d) when the value satisfies a dosing condition, actuating the micro-pump to dispense a predetermined micro-dose of the intervention agent; and (e) contemporaneously generating an electronic audit record comprising the unique identifier, the process-parameter value, the dosing condition and the micro-dose, and storing the record in a tamper-evident, append-only ledger suitable for regulatory audit. 2.(Tamper-evident, dependent) The method of Claim 1, wherein the electronic audit record is stored in at least one of: (i) a cryptographically hashed append-only ledger, (ii) a write-once-read-many file system, or (iii) a secure blockchain. 3. (Lookup table) The method of Claim 1 or 2, wherein the stored threshold is part of a lookup table that maps multiple ranges of the process-parameter to respective micro-dose volumes. 4. (Hot-swap / purge) The method of any of Claims 1–3, wherein the controller of step (b) automatically opens a bypass valve upon cartridge removal, installs a replacement cartridge while the process remains online, and executes an automatic purge and re-prime cycle of the replacement cartridge completed in ≤ 30 seconds before the bypass valve recloses.

5. (Optional AI) The method of any of Claims 1–4, further comprising retraining a machine-learning model on accumulated sensor and dosing data and, when model accuracy exceeds a residual-error threshold γ, using the model to predict a deviation of the process-parameter before the deviation exceeds a tolerance ε, wherein step (d) dispenses the micro-dose responsive to the prediction. 6. (Digital-twin validation) The method of any of Claims 1–5, further comprising replaying historical sensor streams in a digital-twin environment, computing a residual error, and preventing deployment of the retrained model until the residual error is $\leq \gamma$. 7. (Specific ML architecture) The method of Claim 5 or 6, wherein the machine-learning model is a bidirectional long-short-term-memory neural network that consumes at least 20 immediately preceding sensor readings as input features. 8. (Bioreactor pH application) The method of any of Claims 1–7, wherein the intervention agent is Tris base delivered to a cell-culture bioreactor, the method maintaining pH within ± 0.03 units for at least 95 % of run-time and reducing buffer consumption by at least 10 % relative to proportional-integral-

derivative control. 9. (CHO 100-L embodiment) The method of Claim 8, wherein the bioreactor is a 100-litre fed-batch Chinese-hamster-ovary cell-culture process. 10. (CMP inhibitor application) The method of any of Claims 1–7, wherein the intervention agent is an oxidation inhibitor ramp-delivered in a copper chemical-mechanical-polishing line, thereby reducing scratch defects of ≥ 0.5 μm by at least one order of magnitude and reducing slurry consumption by at least 10 %. 11. (UF membrane bio-fouling application) The method of any of Claims 1–7, wherein the intervention agent is sodium hypochlorite dosed downstream of an ultrafiltration membrane, lowering trans-membrane-pressure rise due to bio-fouling by at least 15 %.

System / device claims

12. (Independent — deterministic core) An adaptive-intervention control system comprising:

(a) a plurality of interchangeable intervention cartridges, each cartridge including (i) at least one in-line sensor, (ii) a reagent reservoir, (iii) a micro-pump capable of ≤ 10 µL micro-doses with ± 2 % accuracy, and (iv) non-volatile memory storing a unique identifier and calibration data; (b) a data-acquisition module configured to receive real-time sensor data from each cartridge; (c) a comparator that compares each process-parameter value with a stored threshold fixed in memory; (d) a dosing interface that issues a drive signal to the micro-pump when the comparator determines the threshold is satisfied; and (e) an audit engine that, contemporaneously with each drive signal, generates an electronic audit record comprising the unique identifier, the process-parameter value and the micro-dose, and stores the record in a tamper-evident, append-only ledger suitable for regulatory audit

13. (Tamper-evident, dependent) The system of Claim 12, wherein the audit engine stores each electronic audit record as a tamper-evident data structure by computing a cryptographic hash of the sensor data, dosing command and cartridge identifier and publishing the hash to an immutable ledger.

14. (Lookup table) The system of Claim 12 or 13, wherein the stored threshold is part of a lookup table mapping multiple parameter ranges to respective micro-dose volumes. 15. (Hot-swap / purge) The system of any of Claims 12–14, further comprising logic that, upon cartridge removal, opens a bypass valve, executes an automatic purge and re-prime cycle on a replacement cartridge and recloses the bypass valve within ≤ 30 seconds.

16. (Self-calibration fault) The system of any of Claims 12–15, wherein each cartridge includes firmware that disables actuation when its internal self-calibration residual exceeds threshold β (as defined in the specification Glossary) and transmits a fault status to the dosing interface.

17. (Optional AI) The system of any of Claims 12–16, further comprising a predictive-analytics processor retrained on accumulated sensor data and configured to generate a prediction of future deviation of the process-parameter before the deviation exceeds a tolerance ε, the dosing interface being further configured to issue the drive signal responsive to the prediction.

18. (Digital-twin gate) The system of Claim 17, further comprising a replay engine that replays historical sensor streams, computes a residual error, and prevents deployment of a retrained model until the residual error is ≤ γ.

19. (Frangible tamper seal) The system of any of Claims 12–18, wherein each cartridge comprises a laser-etched frangible cap that, when removed, mechanically actuates a switch driving a secure-disable pin on the cartridge memory, thereby preventing the cartridge's reuse without factory re-provisioning.

Cartridge / kit / manufacturing 20. Cartridge A self-contained, replaceable intervention cartridge comprising: (a) a USP Class VI gamma-stable housing; (b) at least one in-line sensor; (c) a reagent reservoir; (d) an electronically driven micro-pump capable of ≤ 10 µL micro-doses; (e) a micro-controller; (f) non-volatile memory storing a unique identifier, calibration constants and a cumulative dose counter; (g) a sterile quick-connect interface that electrically and fluidically disengages the sensor and micro-pump in a single motion; and (h) a frangible tamper ring that, upon breakage, drives a disable line invalidating the unique identifier. 21. Kit A kit comprising (i) a manifold having at least three sterile quick-connect sockets fluidically coupled to a common supply line and electrically coupled to a daisy-chain data bus, and (ii) at least two cartridges according to Claim 20 pre-filled with mutually different intervention agents. 22. Manufacturing method A method of manufacturing the cartridge of Claim 20, comprising laser-welding a piezo-micro-pump outlet to a PEEK reservoir port, programming the unique identifier and calibration constants into the non-volatile memory, and gamma-irradiating the assembled cartridge to at least 25 kGy. ____

§ 112(f) means-plus-function claim 23. An intervention cartridge comprising: (a) means for sensing a process parameter; (b) means for dispensing an intervention agent responsive to a control signal; (c) means for non-volatile storage of identification and calibration data; and (d) means for communicating bidirectionally with a host controller; wherein said means cooperatively operate to maintain the process parameter within a predefined target range. Corresponding structure is described in paragraph [0011] and FIG. 1 (reference numerals 110, 130, 160) and in Listing 1 of the specification.