

Digital Bioprocessing

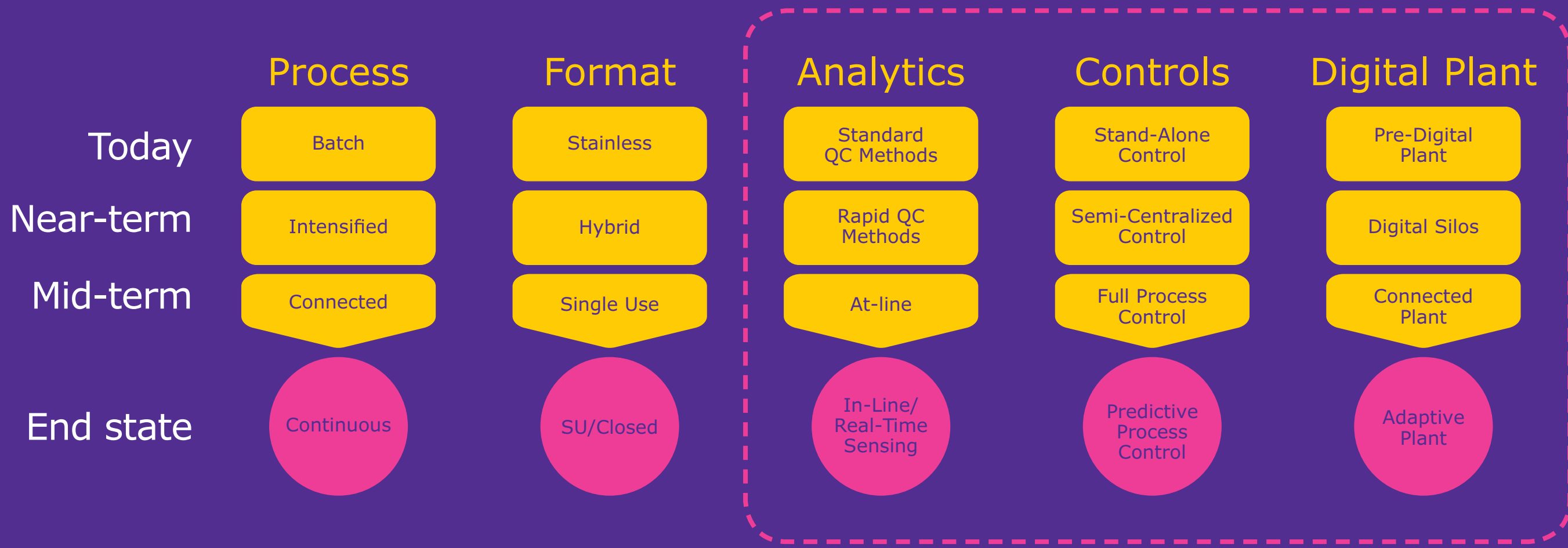
Reference Guide

Market trends, business drivers and key enabling technologies for the future of bioprocessing*

*BioPhorum Operations Group (BPOG) Technology Roadmap



Evolutionary journey across many disciplines to achieve automated facility



Digital Transformation Opportunities for Bioprocessing

Today

Traditional Bioprocessing

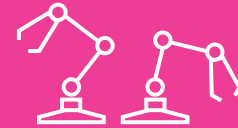


Data collection & management

time and labour that can be used for other value added activities

Manufacturing equipment

works independently and cannot communicate with each other



Paper-based data review process

lengthens product release time



Manual process control

can lead to mistakes

Tomorrow

Digital Bioprocessing

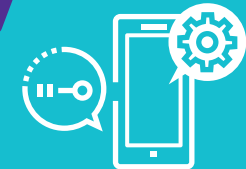


Central data repository

User friendly dashboards give easy access to gathered data



generates digital documentation of all critical process parameters



automatic data analyzing process simulation



Acceleration of scale-up process

virtual prediction



Higher level of automation

at an affordable cost executes and verifies process steps



Predictive maintenance



self-guided just-in-time training



strengthens business-to-business relations

employees can focus on work

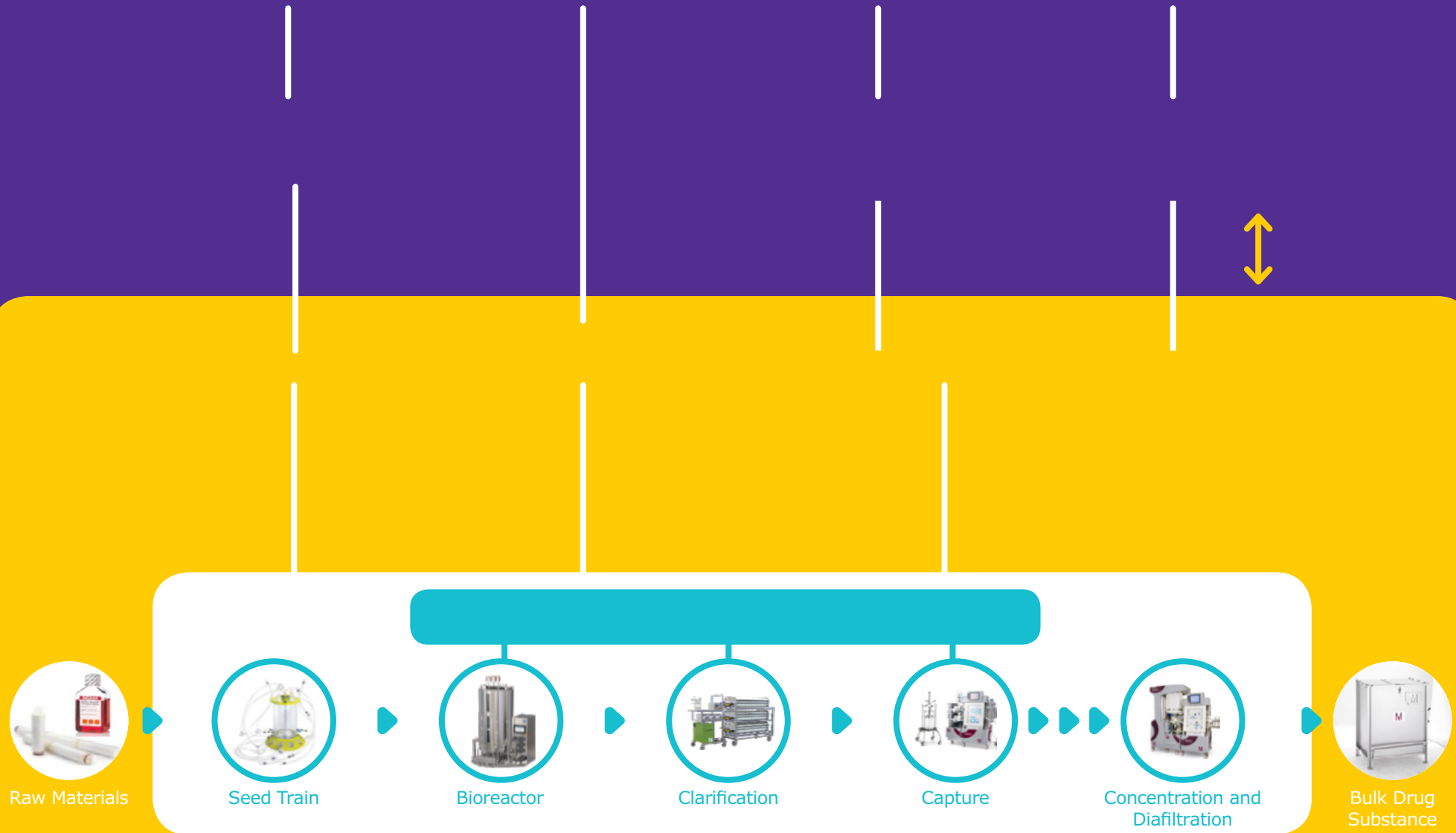


saves time



less mistakes

Functional hierarchy

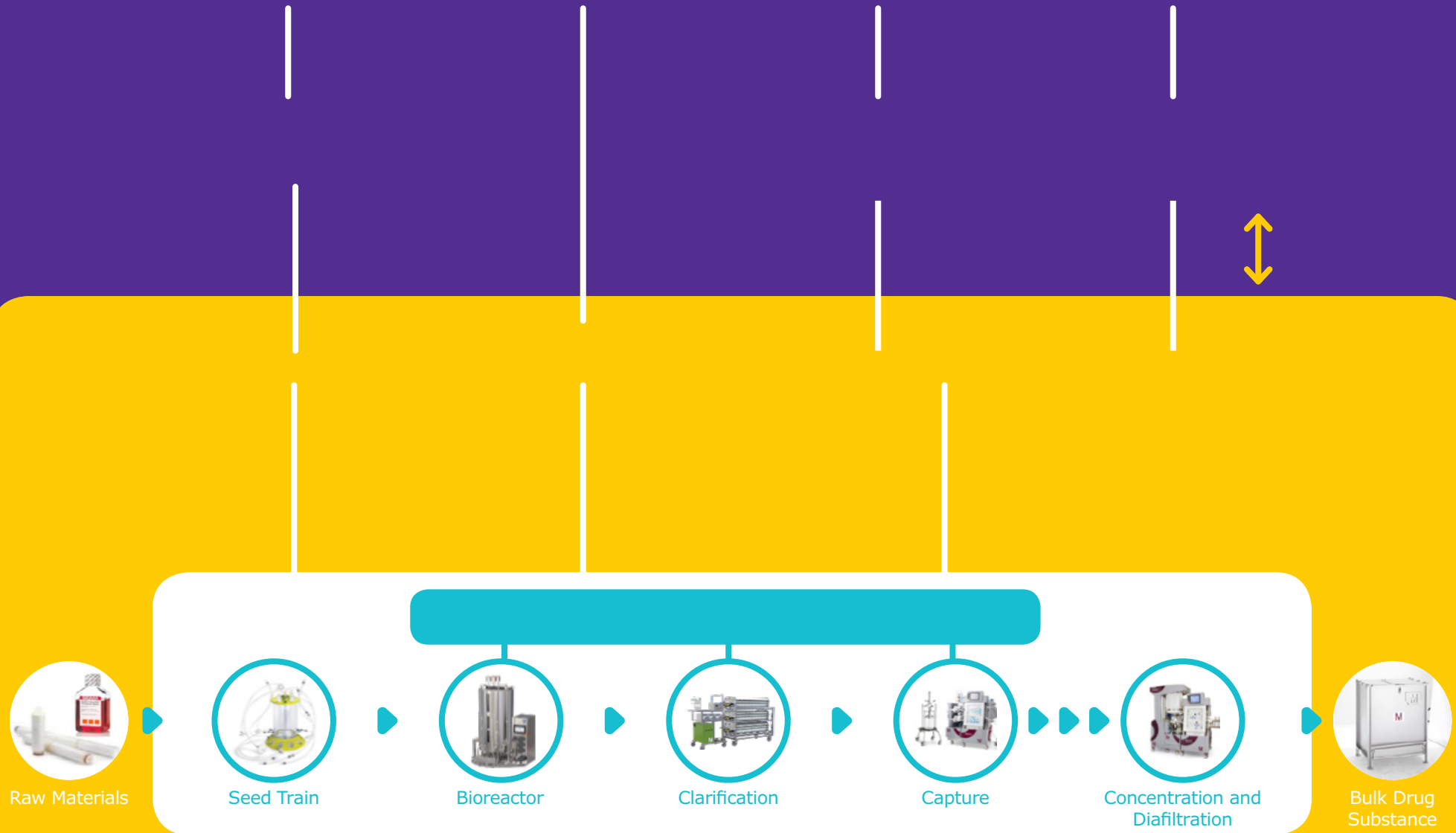


The Digital Bioprocessing Dictionary

Click on the terms in the graphic to get corresponding explanations

* Items in pink are outside the scope of the Software, Automation & Analytics Initiative

Functional hierarchy



The Digital Bioprocessing Dictionary

SRM/CRM:

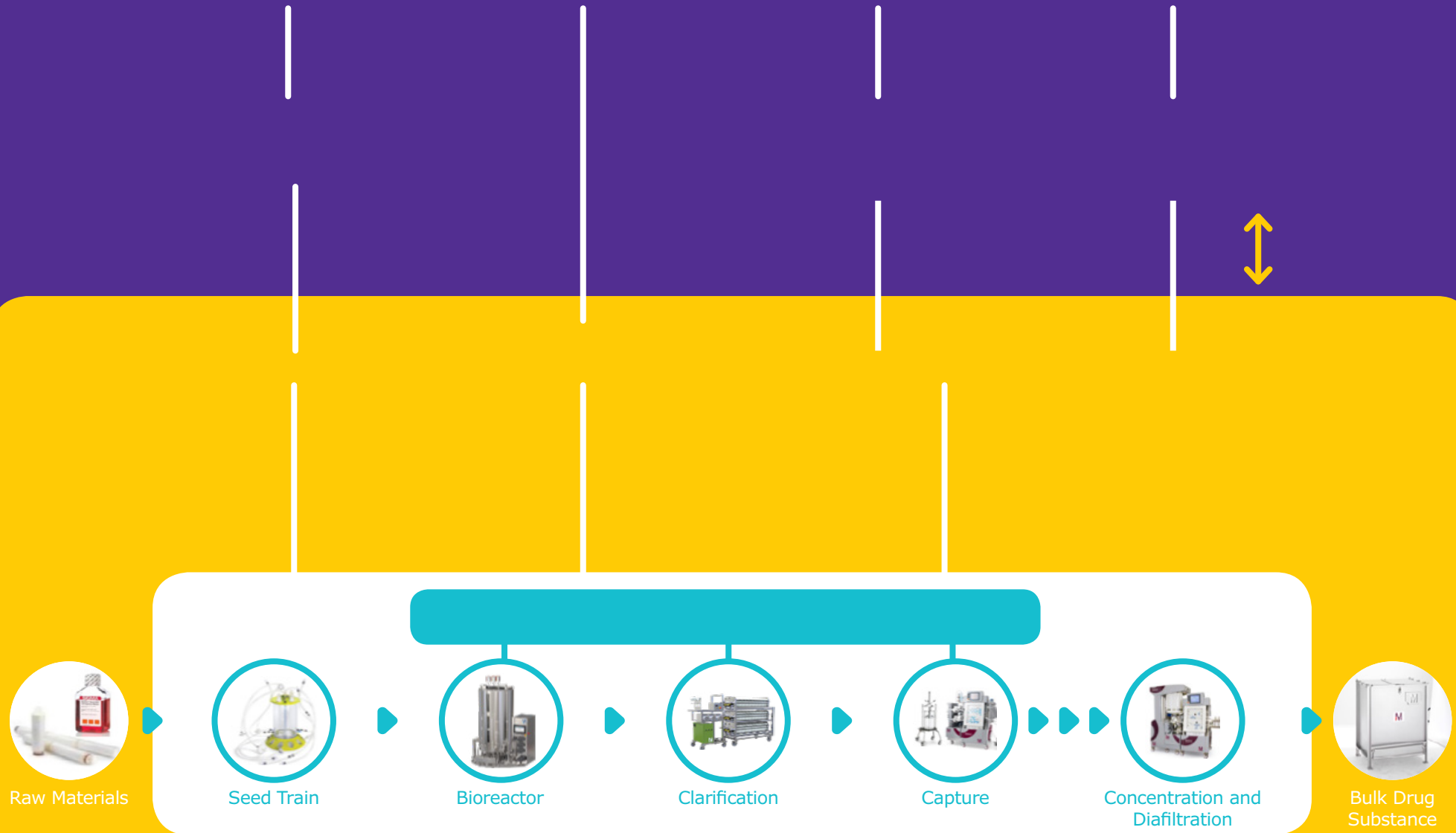
Commercial side (SFDC).

SRM: Supplier Relationship Management

CRM: Customer Relationship Management.

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Functional hierarchy



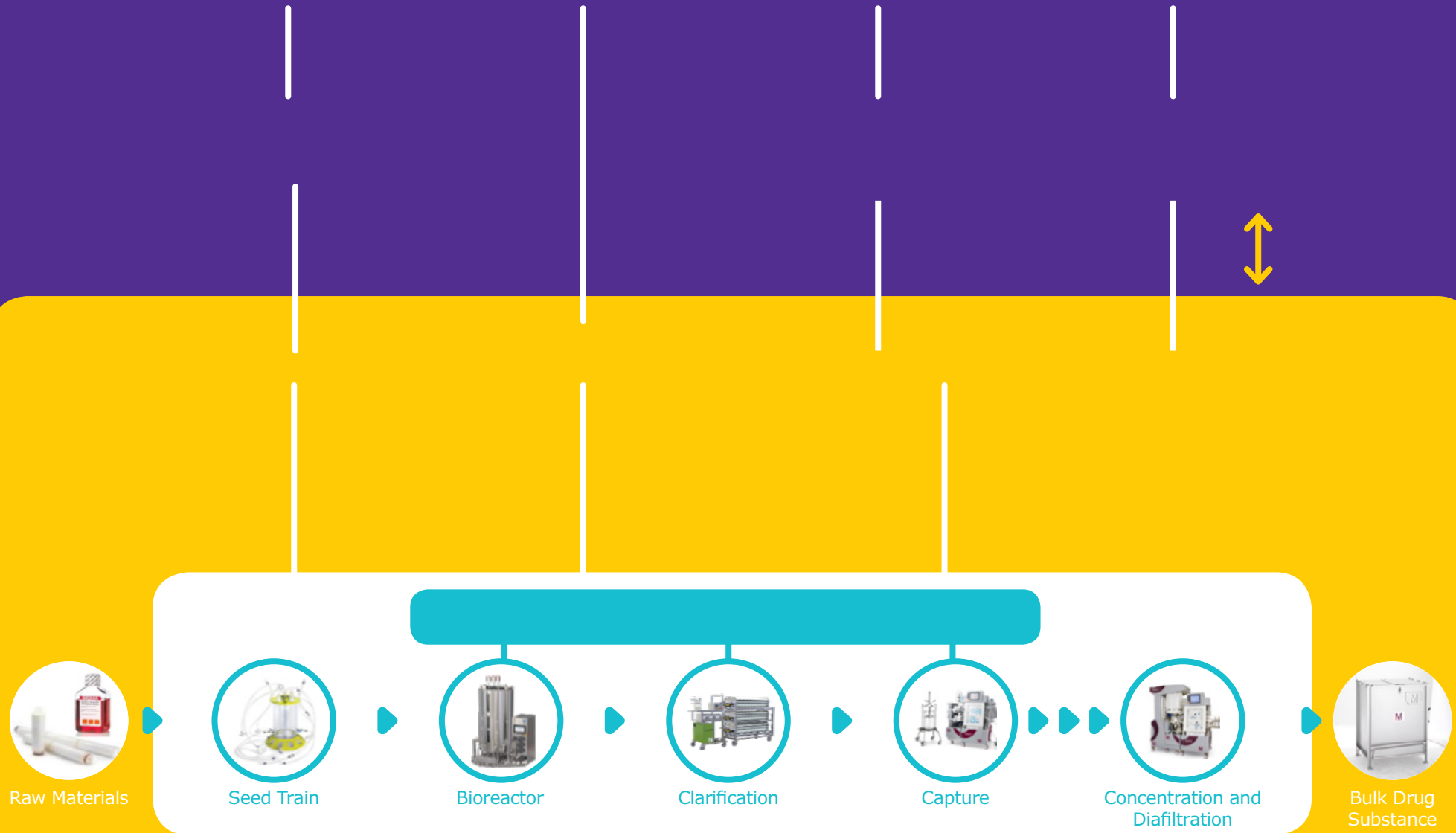
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Enterprise Resource Planning (ERP):

Based on SAP® or Oracle®, is a process by which a manufacturer manages and integrates areas such as planning, purchasing, inventory, sales, marketing, finance and human resources. Manages production planning to determine when you need raw materials, people, finished goods. Able to take into account lead times, QC lead time, shipping time, etc. Resides at a corporate level so looking at multiple locations; time horizon different; does not know status and availability of specific resources.

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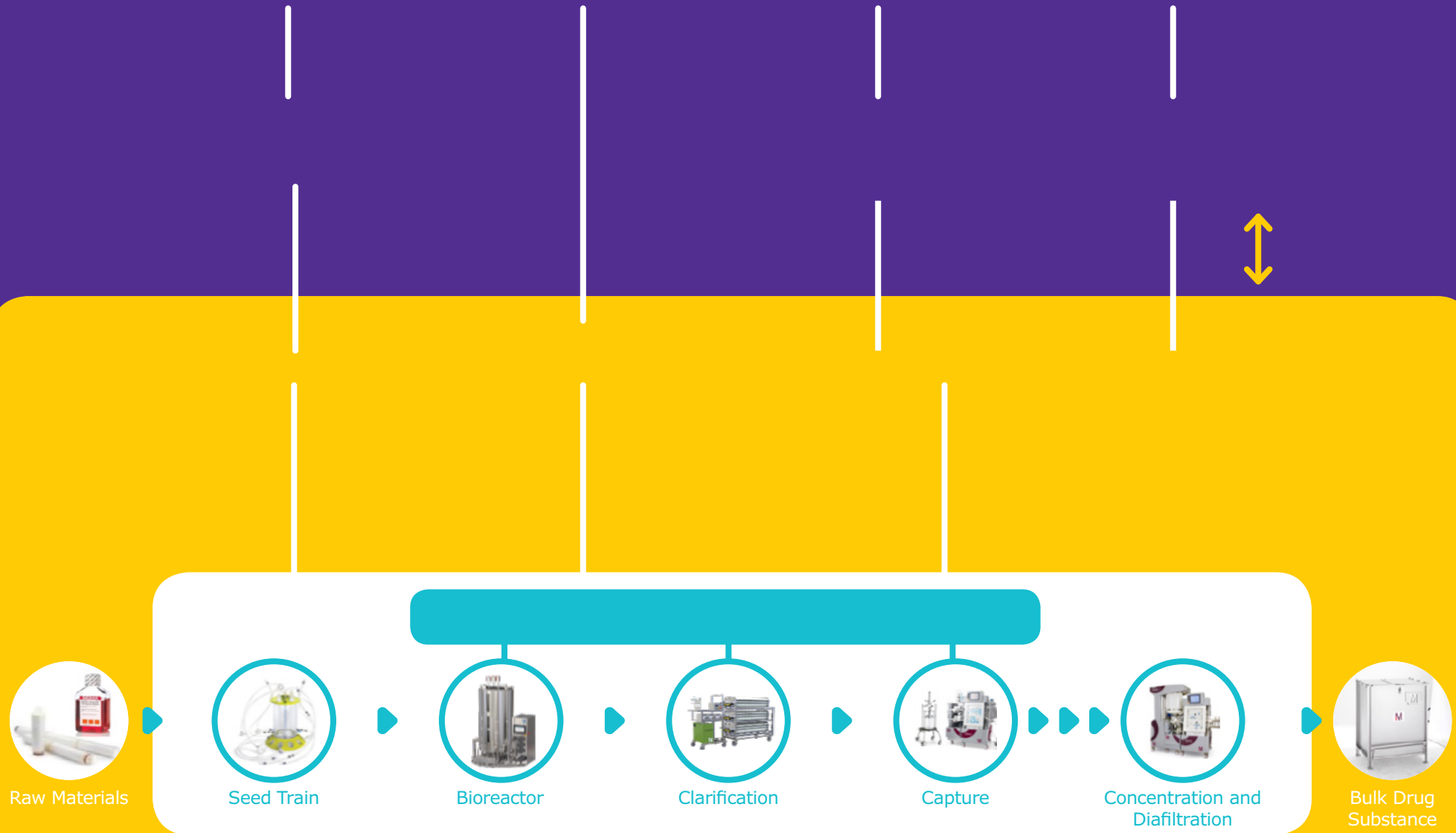
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Dashboard:

A data visualization tool that displays the current status of metrics and key performance indicators (KPIs) for an enterprise. Dashboards consolidate and arrange numbers, metrics and sometimes performance scorecards on a single screen.

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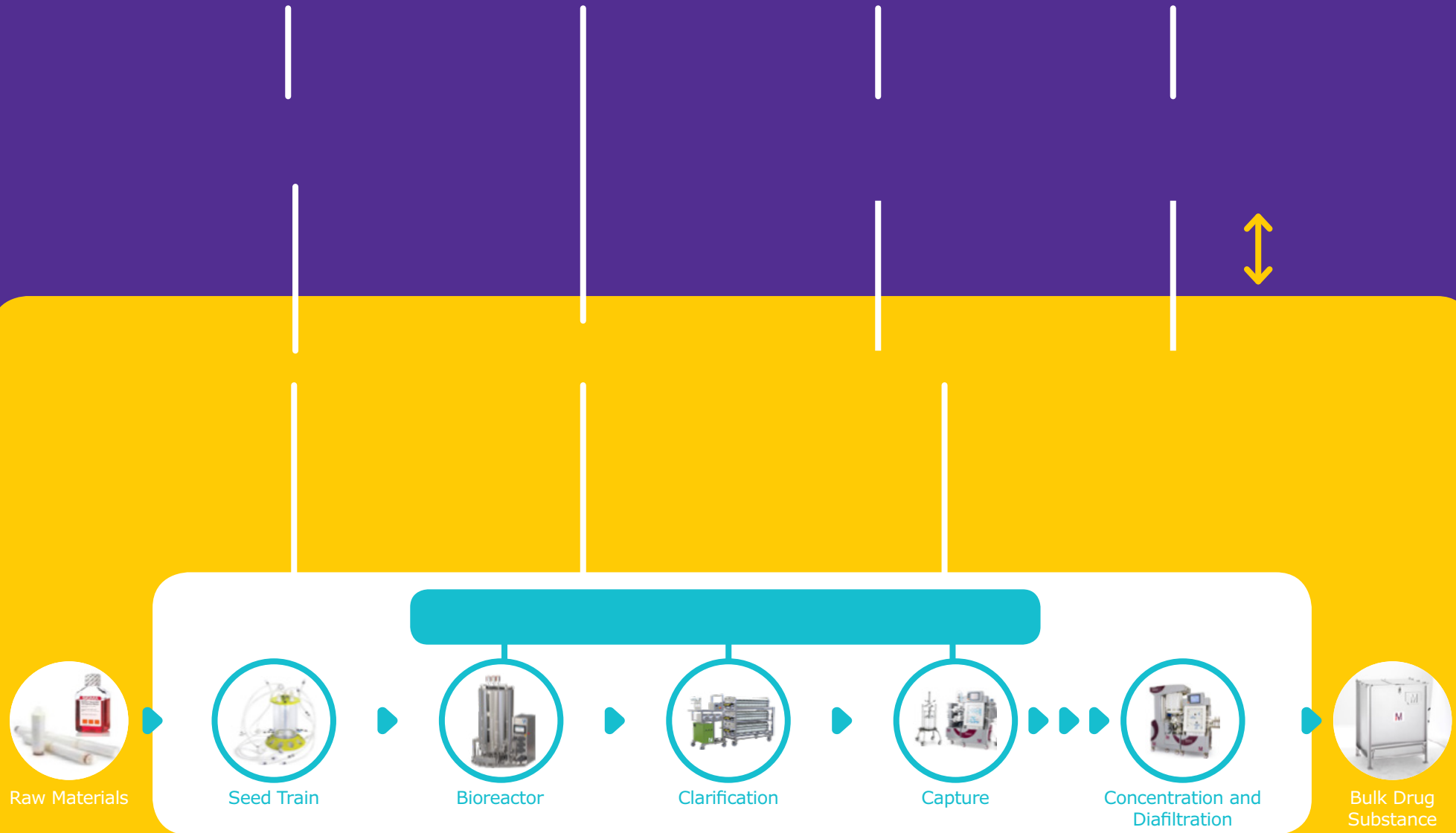
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Cloud:

A global network of servers, each with a unique function. The cloud is not a physical entity, but instead is a vast network of remote servers around the globe which are hooked together and meant to operate as a single ecosystem. These servers are designed to either store and manage data, run applications, or deliver content or a service such as streaming videos, web mail, office productivity software, or social media.

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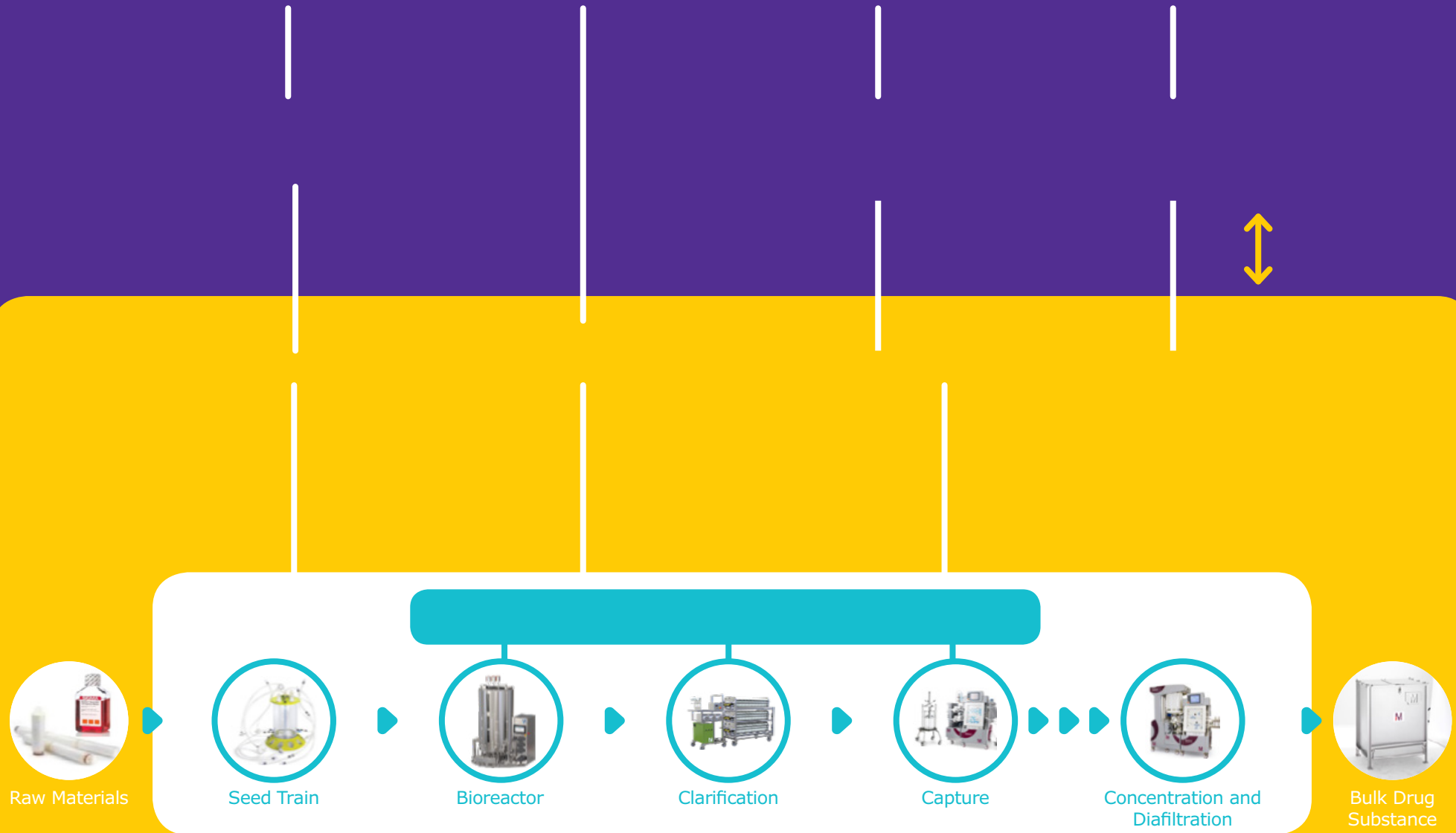
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Enterprise Network:

Company's overall intranet.

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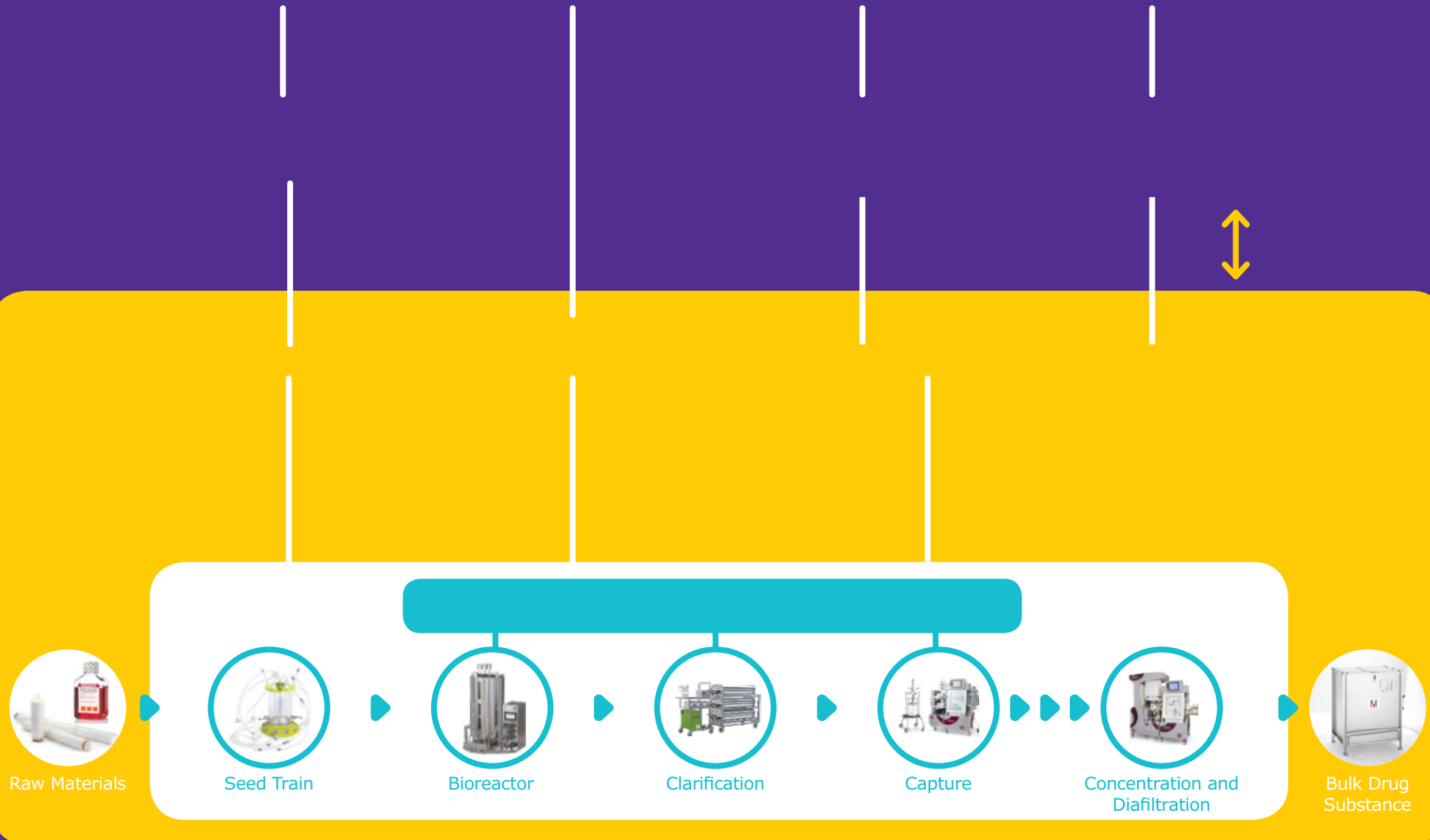
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Manufacturing Execution System (MES):

Computerized systems used in manufacturing to track and document the transformation of raw materials into finished goods. MES works in real time to enable the control of multiple elements of the production process (e.g. inputs, personnel, equipment and support services) at a specific site level. MES is the layer that integrates the business systems (ERP) with plant control systems.

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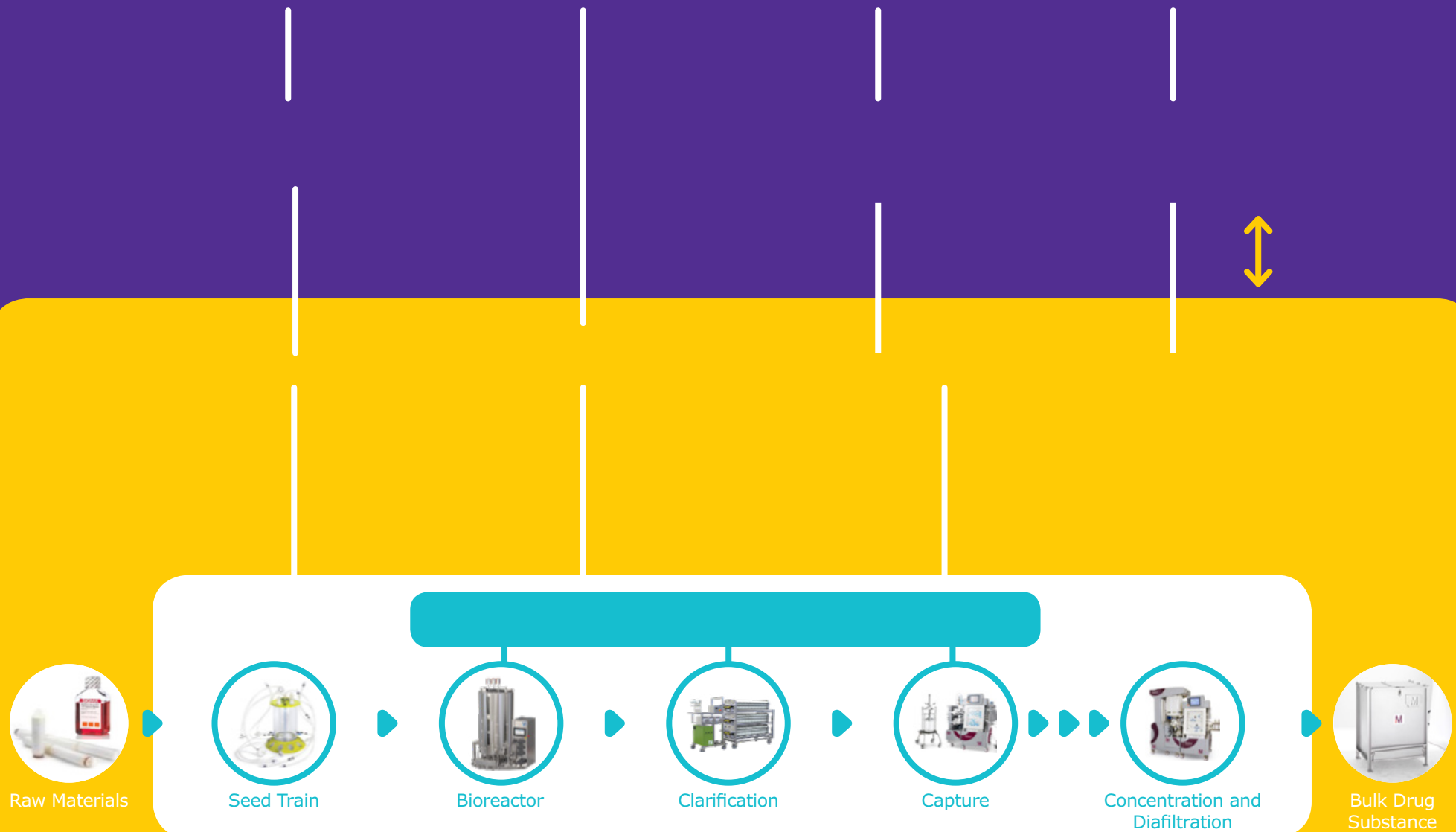
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Historian:

Database software application that logs or historizes time-based process data. Historian software is used to record trends and historical information about industrial processes for future reference. Utilized to create a portion of the batch record; all Critical Process Parameters (CPPs) are recorded in the process historian.

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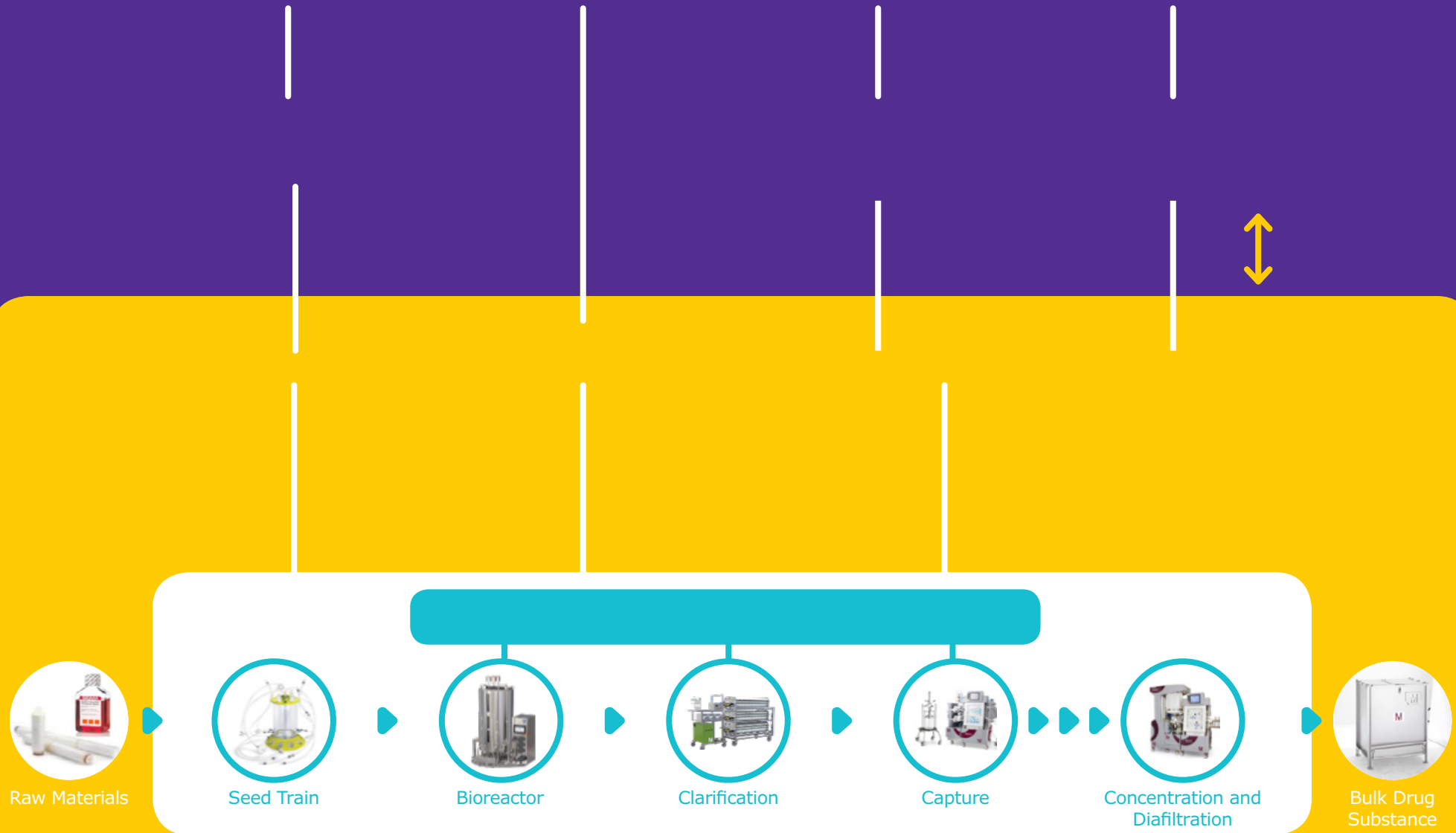
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Lab Information Management System (LIMS):

Focused on QC/analytical applications.

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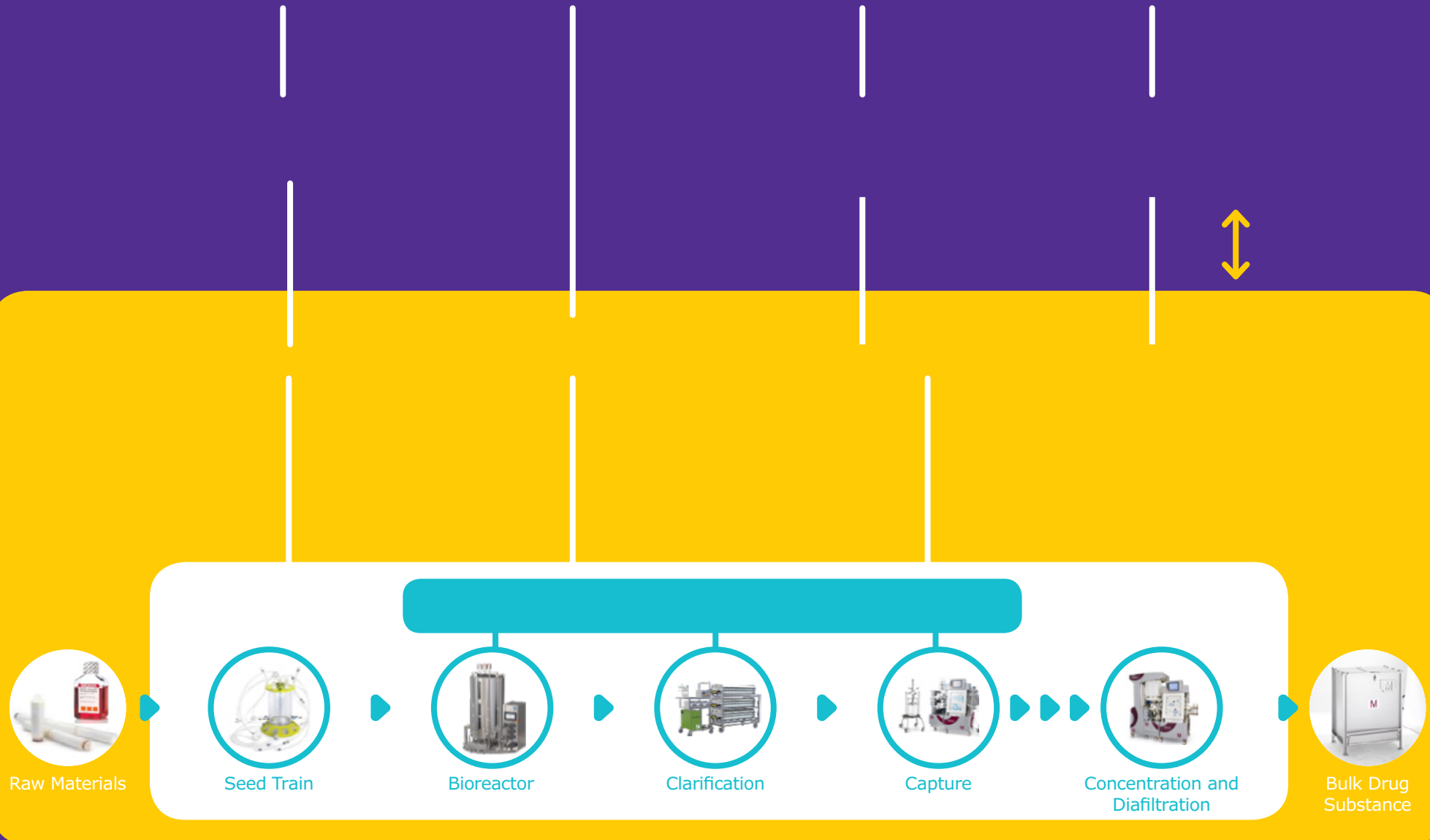
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Paper Glass – editable PDF:

Implementing existing processes and recipes as they are in manual processing within an electronic batch record.

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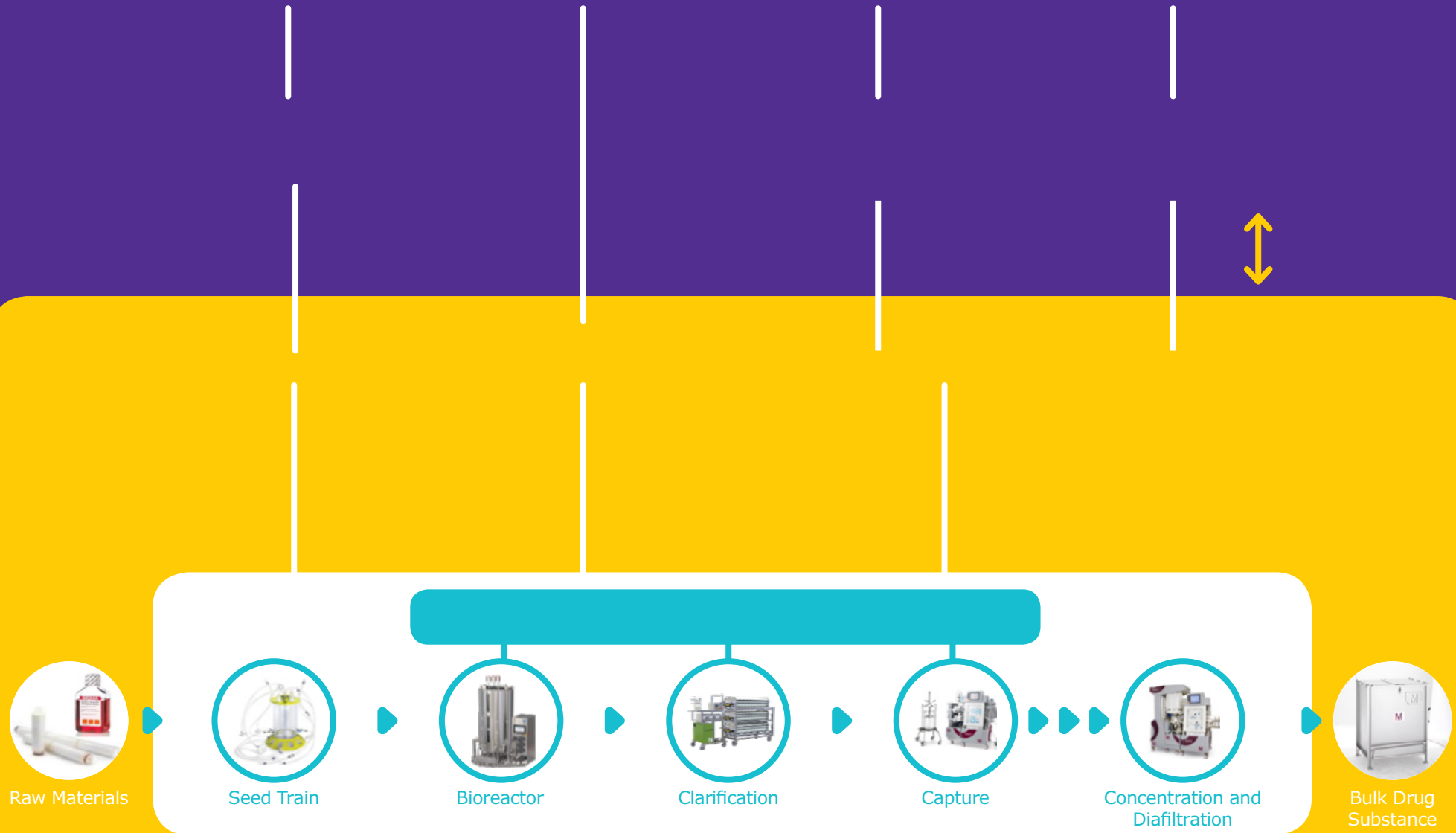
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Manufacturing Network:

Isolated from traditional enterprise network meaning the only way to access it is to be there physically; could still be wired or wireless connection but security is critical; may be able to access it remotely but ONLY by coming through the enterprise network in order to maintain security.

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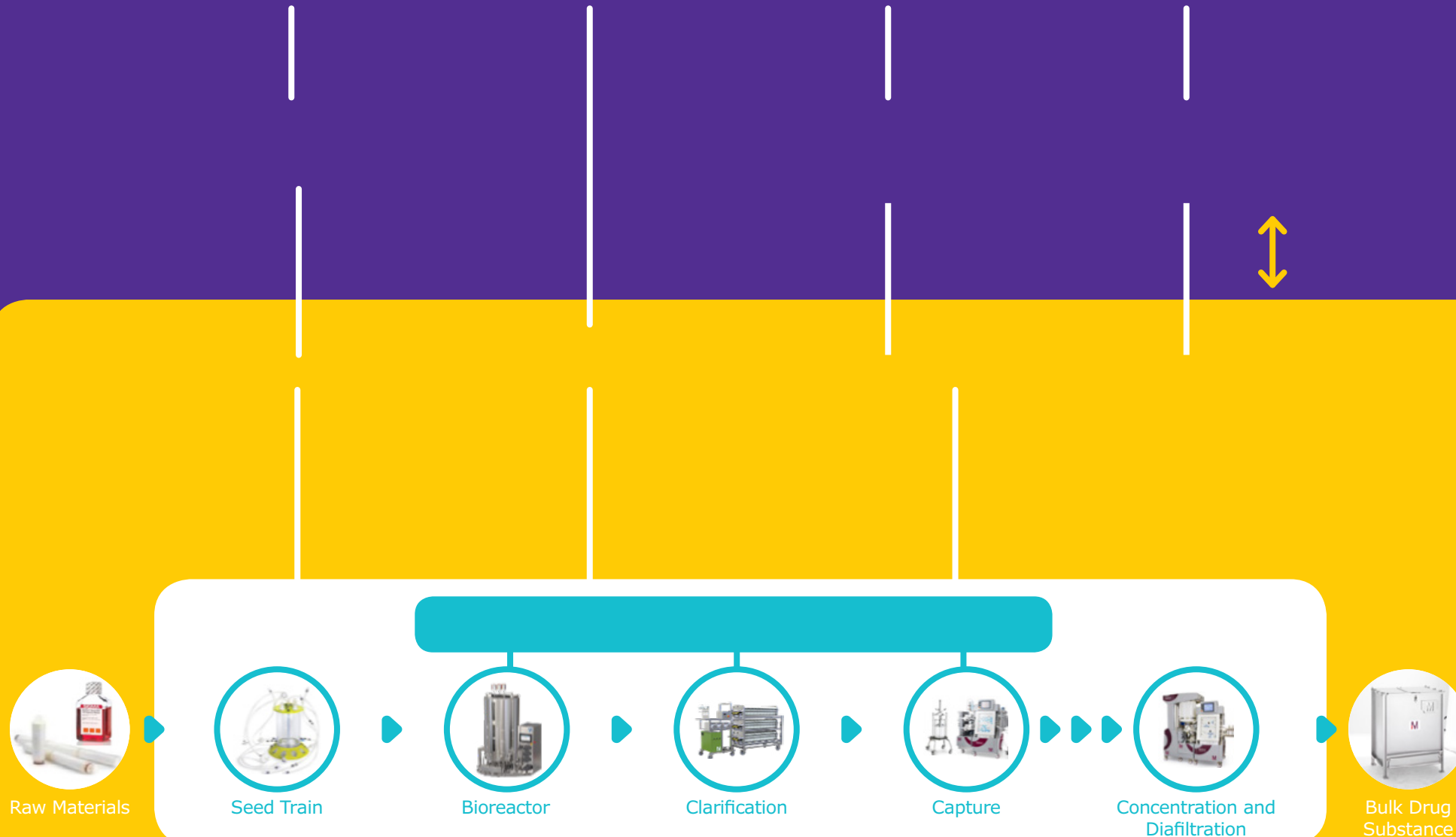
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Human Machine Interface (HMI):

A software application that presents information to an operator about the state of a process and a format where the operator can input control instructions and operating parameters. Typically displayed in a graphical format (Graphical User Interface or GUI).

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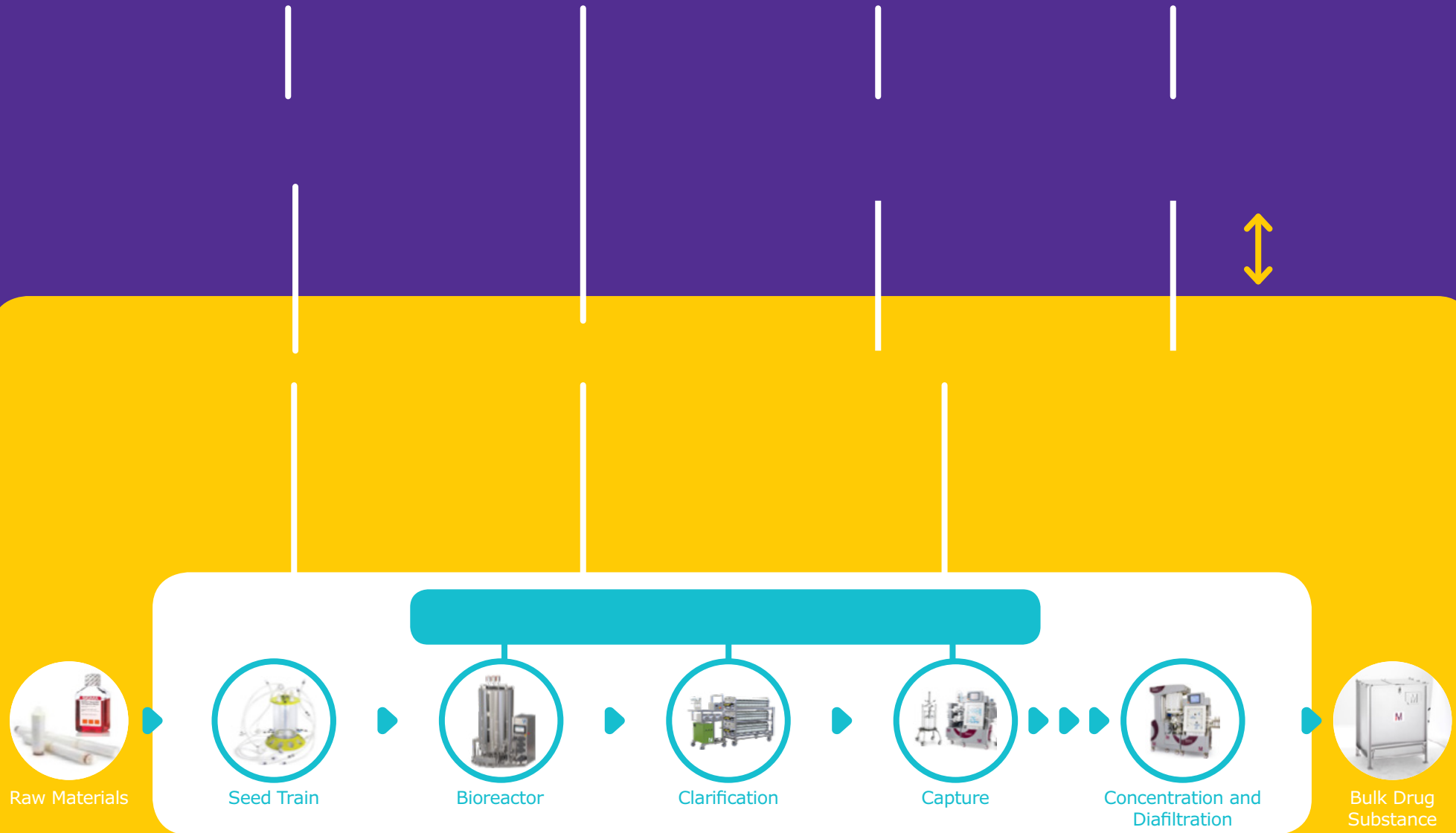
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Process Analytical Technology (PAT):

A methodology in which manufacturers understand their process variability due to raw materials and manufacturing equipment, which of these process parameters are critical to the production of product with the right quality attributes, and then controlling the manufacturing process within the defined limits which will provide a product with the right quality. Three tools are critical for successful PAT implementation:

- 1. Multivariate Data Acquisition and Data Analysis Tools:** typically advanced software packages which aid in the design of experiments, collection of data, and data analysis to show statistically which parameters are critical (utilized during process development).
- 2. Process Analytical Chemistry Tools:** in-line and on-line analytical instruments that measure the critical process parameters, may include NIRS, biosensors, Raman, and others (pH for capture, conductivity for UFDF).
- 3. Continuous Improvement Tools:** Paper systems or software packages that accumulate QC data over time to define where the process is potentially weak or where there are improvement opportunities; possible to be a part of the multivariate software package.

Functional hierarchy



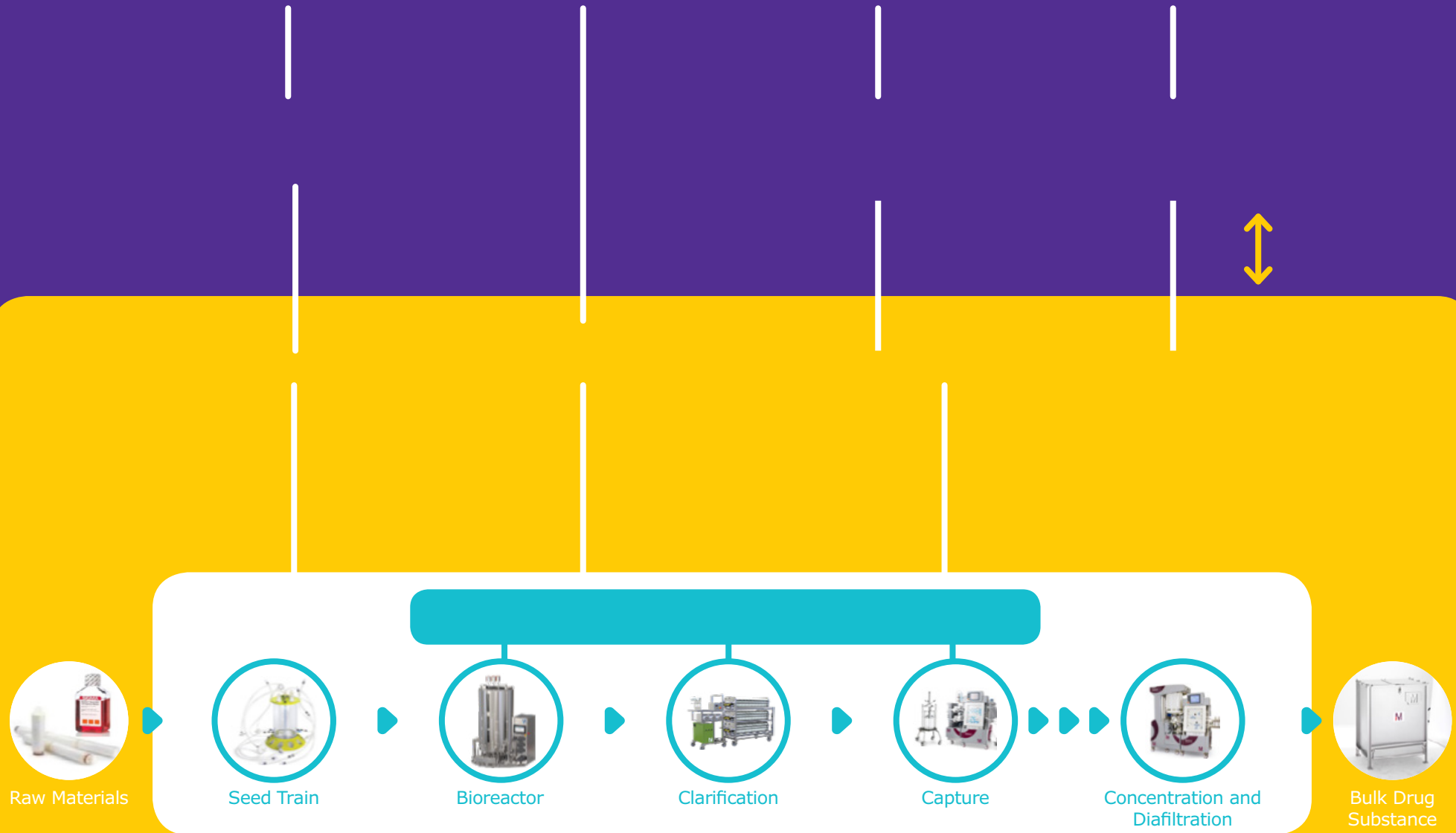
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Distributed Control System (DCS):

A computerized control system for an entire process or plant usually with a large number of control loops, in which individual PLC's are distributed throughout the system. Many times, a PLC will be removed from the unit operation and DCS will control it, unless the DCS is too slow to control a specific unit operation (final fill).

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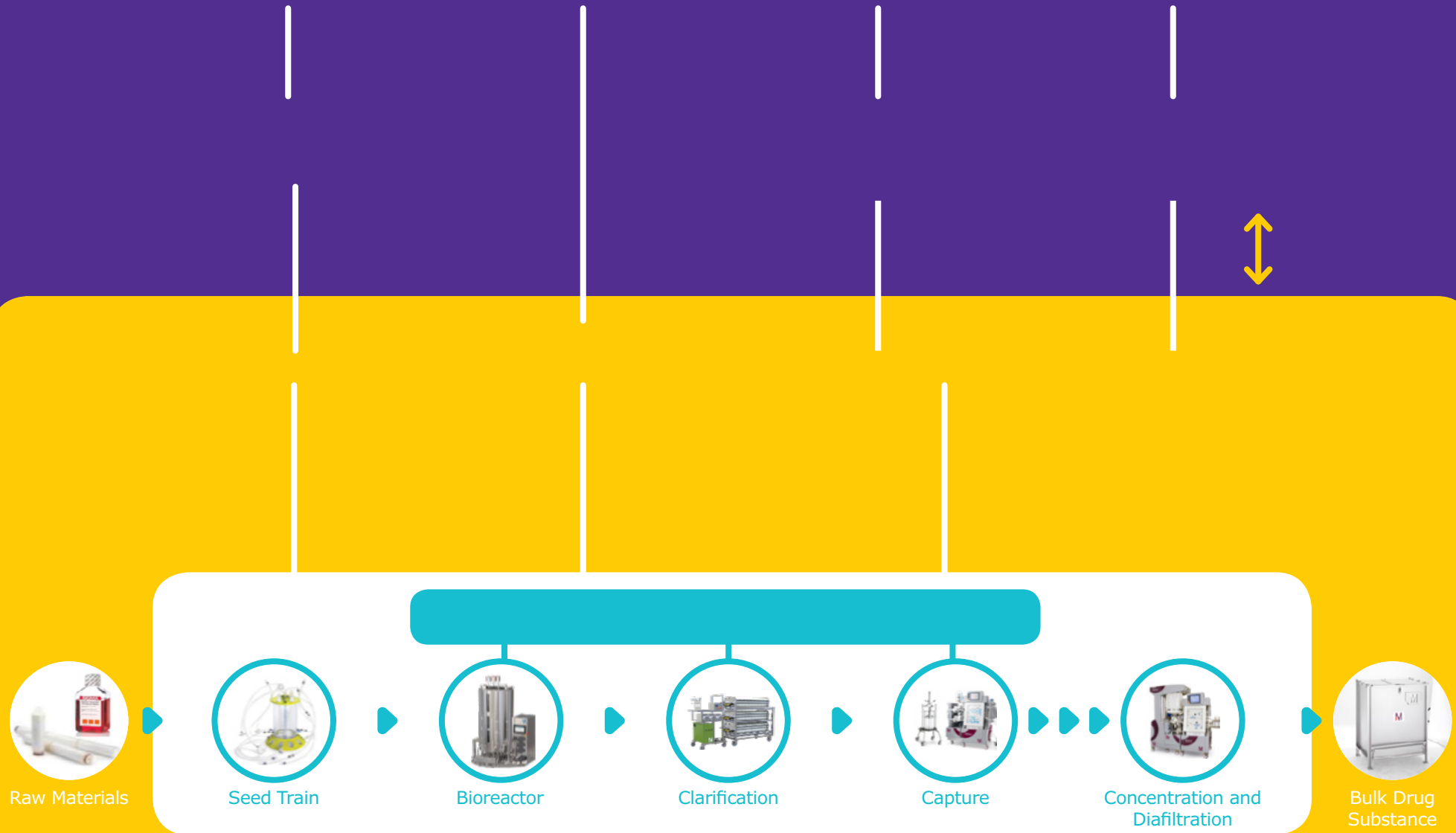
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Programmable Logic Controller (PLC):

An industrial computer used to run individual unit operations, replacing human intervention (open/close valves, pump on/off) and adapted for the control of manufacturing processes, manifested as assembly lines or robotic devices as an example. Typically for any activity that requires highly repeatable/reliable control, ease of programming, and process fault diagnosis.

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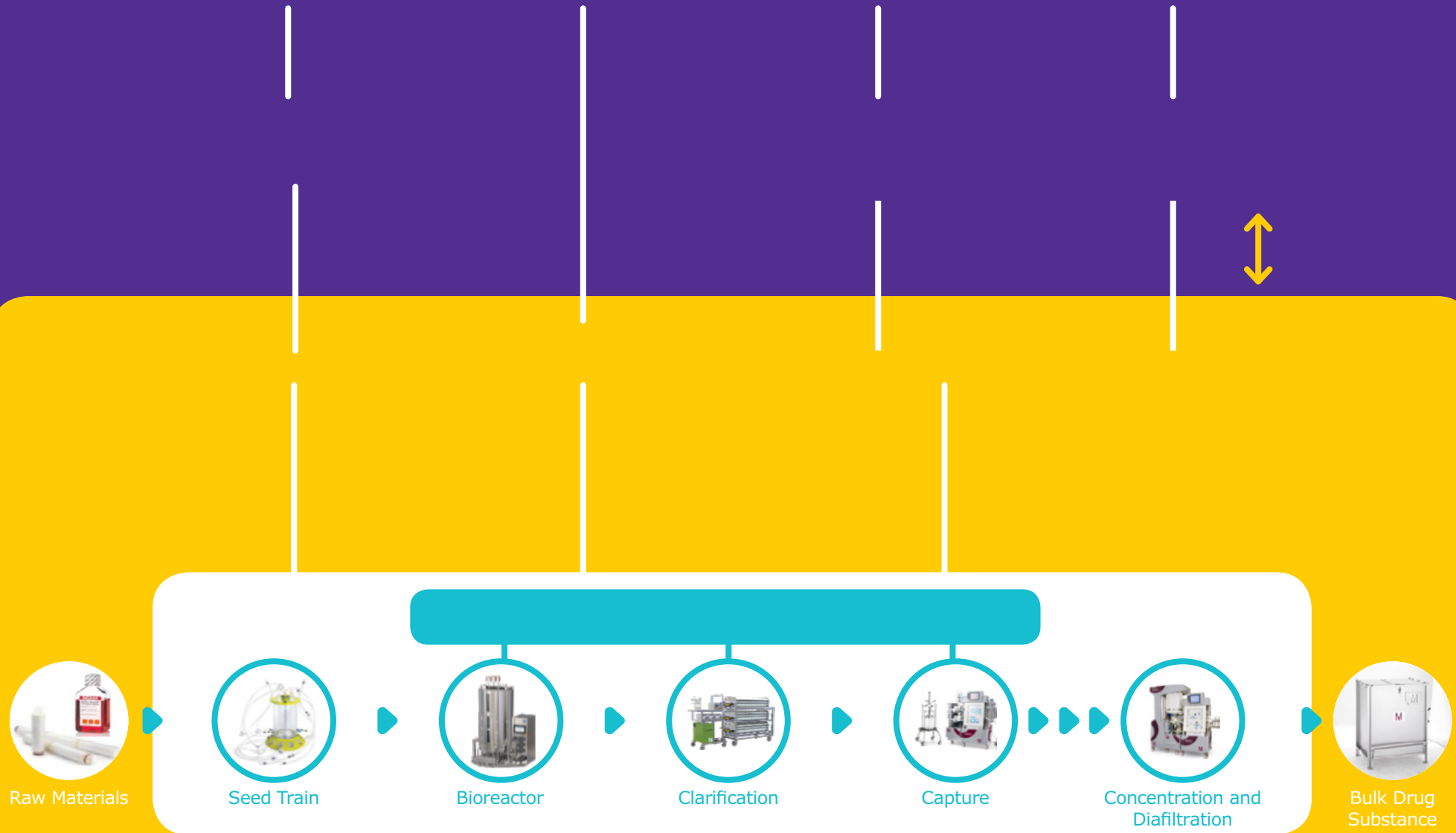
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Sensor:

A sensor is a device that detects and responds to some type of input from the physical environment. The specific input could be light, heat, motion, moisture, pressure, or any one of a great number of other environmental phenomena.

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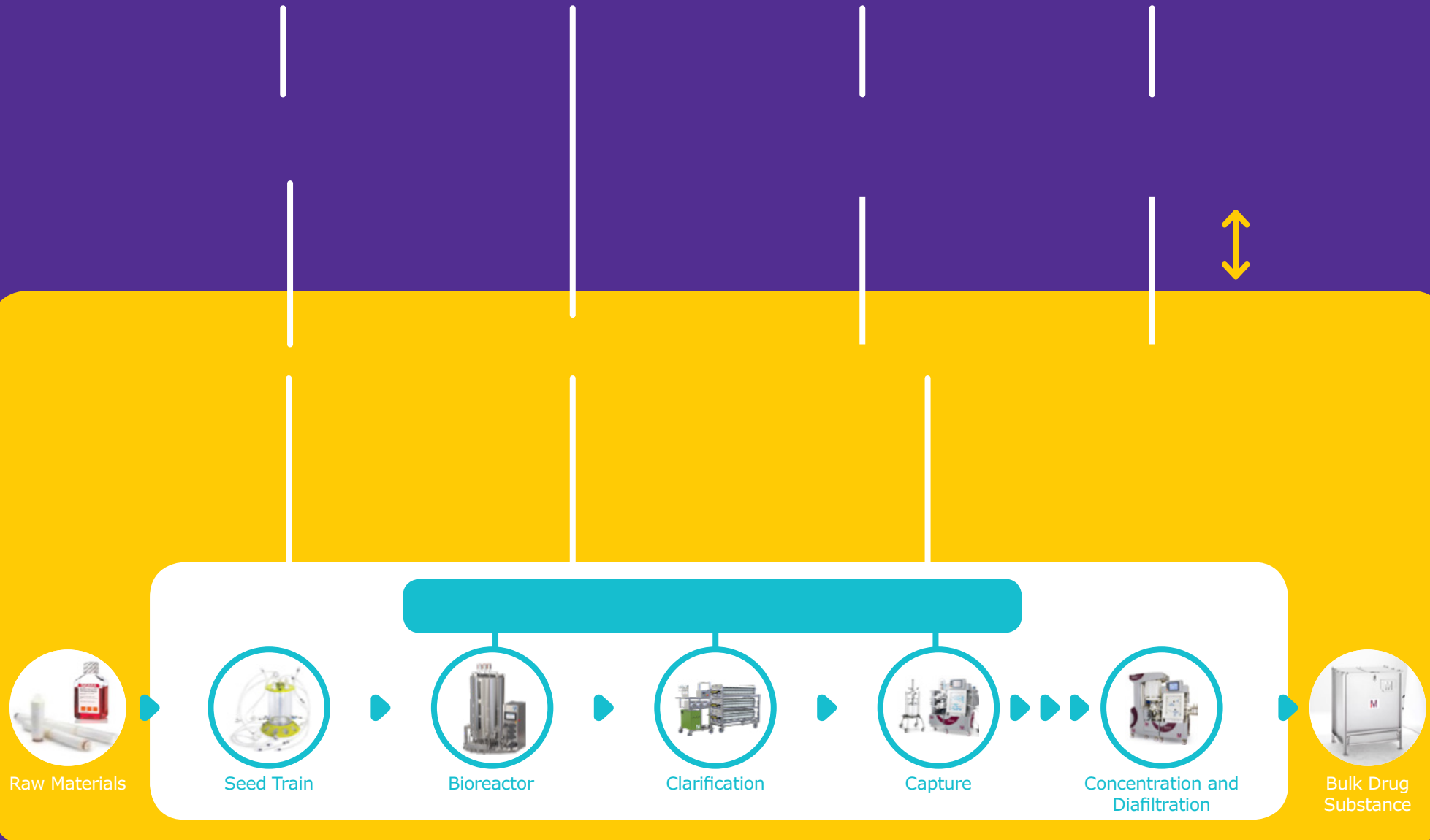
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Control Loop:

Automated action taken on one unit operation based upon an upstream or downstream unit operation input (level, pressure, pH, etc) or within a unit operation.

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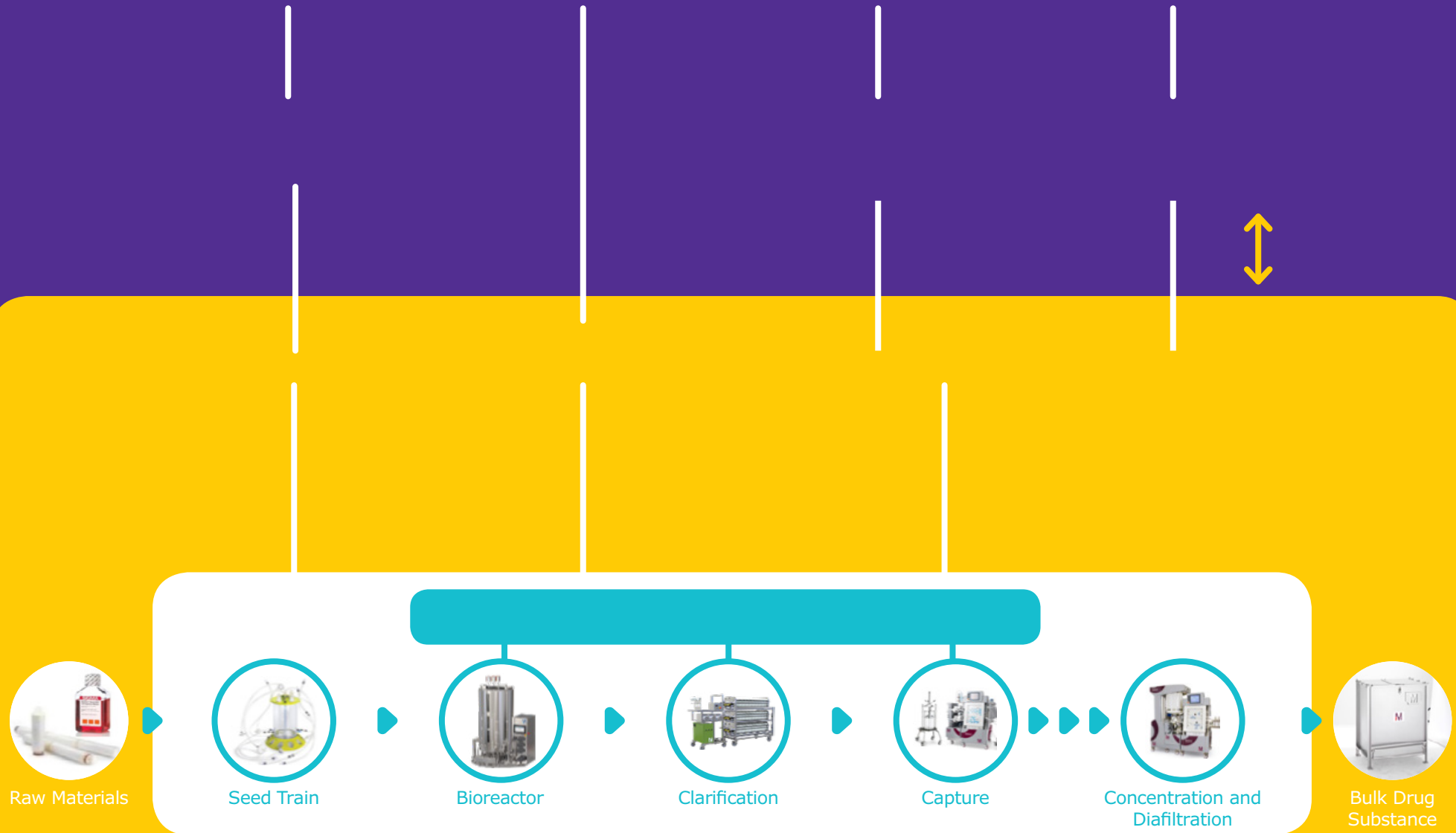
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Supervisory Control and Data Acquisition (SCADA):

An industrial computer system that monitors, controls and provides high level supervision of a process. Utilizes computers, networked data, and graphical interfaces. SCADA systems have grown to become very similar to a DCS in function but uses multiple means of interfacing with the plant. Of particular concern for SCADA systems is cyber-attacks due to their open nature.

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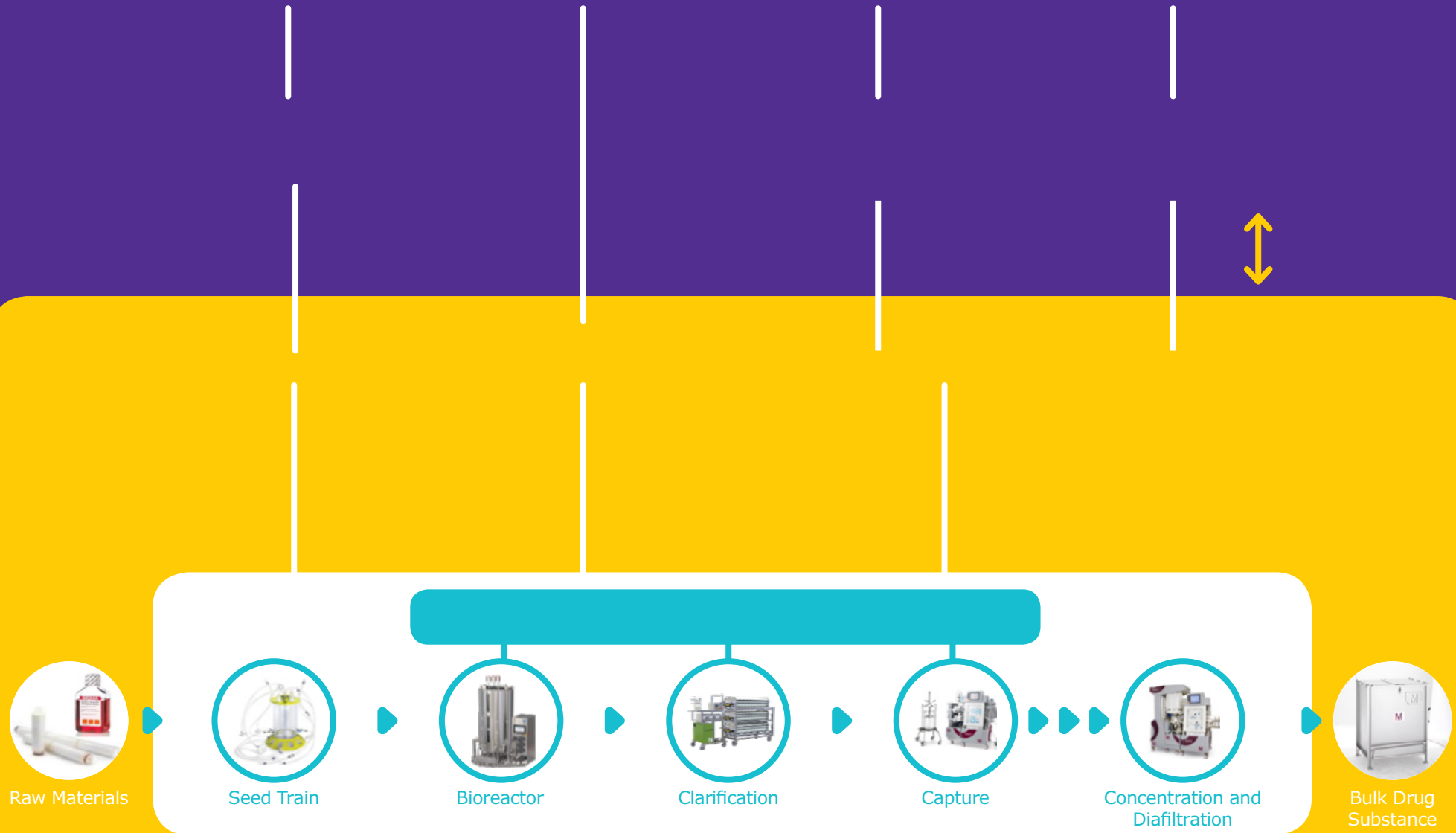
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The Internet of Things (IoT):

A system of interrelated computing devices, mechanical and digital machine devices embedded with electronics, software, sensors, actuators and network connectivity that enables these objects to collect and exchange data over a network without requiring human-to-human or human-to-computer interaction. Some of this could be managed within a cloud (referred to as FOG when you bring the cloud onto your physical premises). Needed to implement the orchestration layer and data management.

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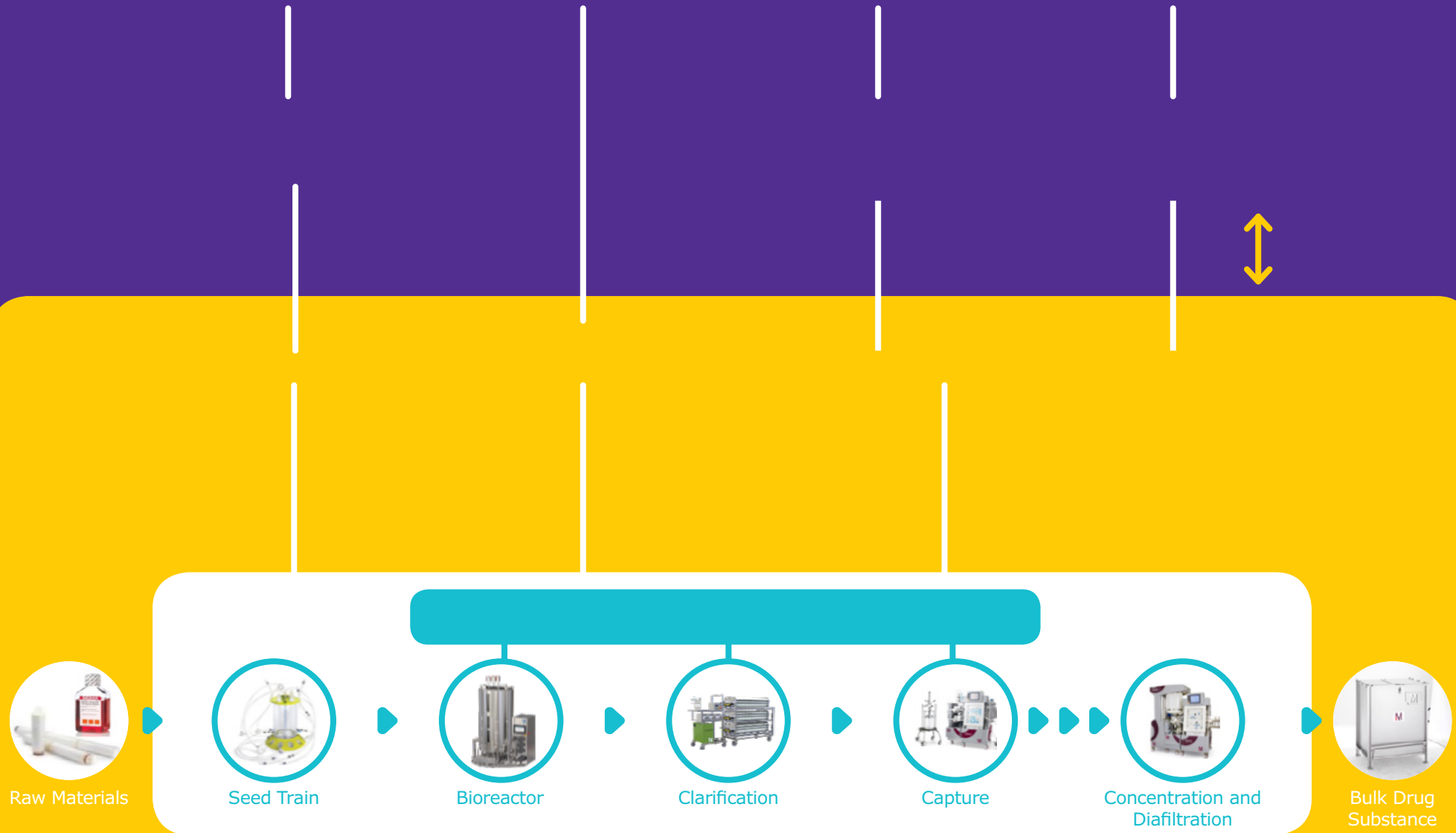
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Unit Operation:

Individual step in the overall manufacturing process (clarification, capture, TFF, etc.). Self-contained piece of equipment and components which CAN include a Programmable Logic Controller (PLC). At commercial scale, commonly referred to as a skid; at lab scale, commonly referred to as a bench top system (for process development or screening).

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The Digital Bioprocessing Dictionary

Orchestration:

Orchestration is the connectivity across unit operations for the collection of process data and/or control of other unit operations. These features are often key features within a distributed control system (DCS).

A software program that manages the interconnections and interactions among cloud based components to align the business request with the applications, data, and infrastructure. Could be a combination of any or all of the following ERP, MES, Historian and HMI.

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* Source: BioPhorum (BPOG) <https://www.biophorum.com/category/resources/technology-roadmapping-resources/introduction/>

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