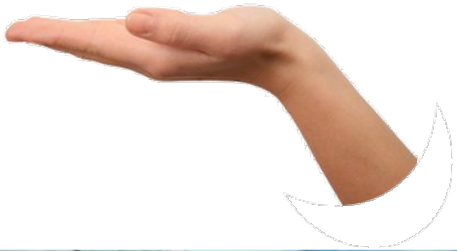
OPERATIONS MANAGEMENT TEAM

UNO SPINOFF DELL'UNIVERSITÀ DEGLI STUDI DI ROMA TorVergata

Standardization in Batch Manufacturing

*Optimizing the Recipe Development Process with **S88 Standard** and the Business and Manufacturing Integration with **S95 Standard***



Applicability of S88/ S95 in Batch processing Industry

Food & Beverage

CPG

Pharma

Pet Food

Speciality Chemical

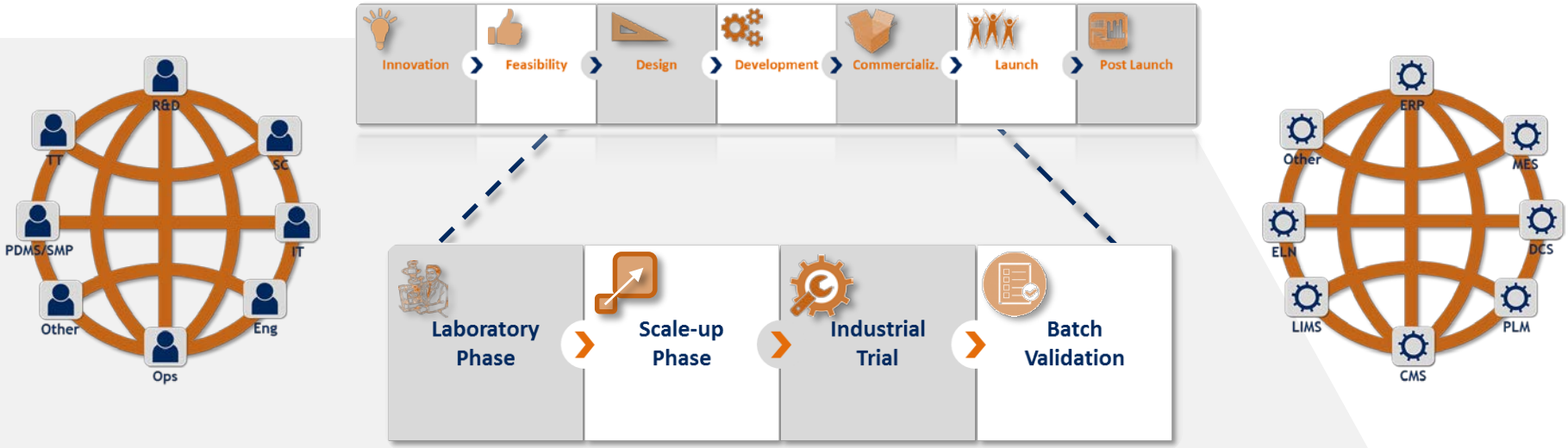
Plastics

Nutra ceutical

Medical Devices

ISA-88: Challenges in batch industry
Focus on NPDI and recipe development

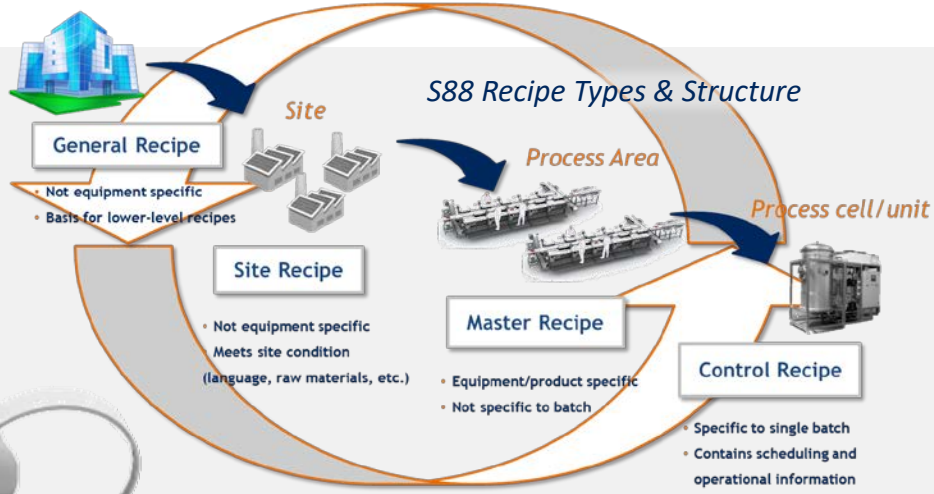
Strategic importance of managing frequent **new product development & introduction, reformulation and cross site tech-transfer**

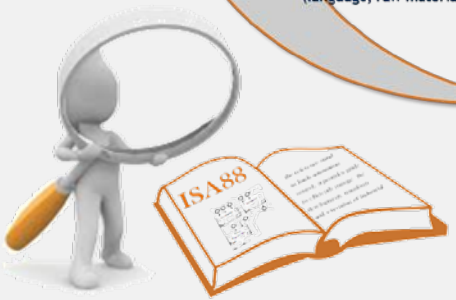


1. Long-lasting **Time to market** of NPDI and reformulations
2. Strenuous **transformation process of "recipes"** from laboratory-based to industrial batch
3. Difficulty in technical transfer of production **among company plants**
4. **Lot wastes & poor yield** during scale-up and industrial validation phase

S88, THE BRIDGE TO OPERATIONAL EXCELLENCE

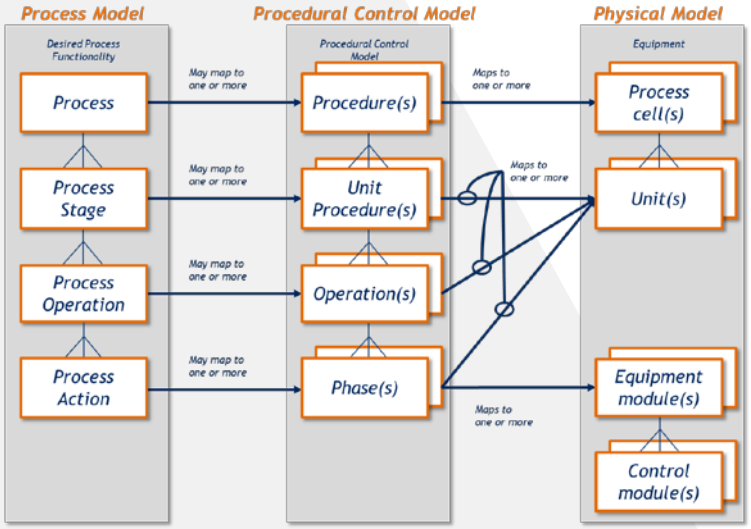
*"S88 (short for ANSI/ISA-88) is the **reference standard in batch automation and control**, it provides guideline to efficiently manage the development, transformation and execution of industrial batch-recipes"*





S88 Recipe Definition:

"The necessary set of information that uniquely defines the production requirements of a specific product"



Hierarchy Reference Model

Part 1	Models and Terminology
Part 2	Data Structures and Guidelines for Language
Part 3	General and Site Recipe Models and Representation
Part 4	Batch Production Records
Part 5	Implementation Models & Terminology for Modular Equipment Control

S88, What does it do

*"S88 is about taking all the activities we perform, breaking them down into **re-usable blocks of information**, then selfishly (and diligently) reusing them wherever we can"*

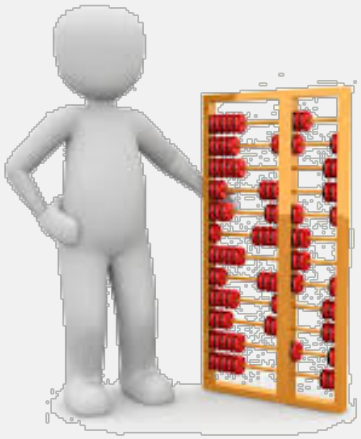
Marc Hooybergs, Global Execution System Director at JnJ

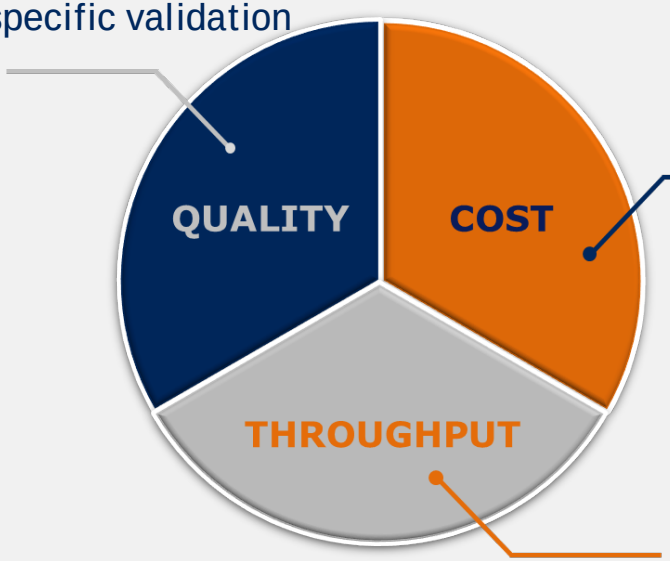
1. Separates the **Recipe** from the **equipment control**
2. Allows **hierarchical recipe management** and process segmentation
3. Improves the ability to transport a recipe **from one system to another**
4. Enables cross-functional alignment on **terminology and methodology**
5. Improves equipment/recipe **long-term maintainability**
6. Simplifies **recipe validation** and cross-site **product transfers**

S88, Benefits

*Adopting S88 guarantees both **technical** and **business advantages**, with impacts on the **development process** and **execution of industrial batch-recipes***

- ✓ Increase yield of chemical processes
- ✓ Increase batch-to-batch consistency
- ✓ Ease Investigation process
- ✓ Reduction time for site specific validation





- ✓ Savings from quality and throughput improvements
- ✓ Revenue opportunity due to faster go-to-market
- ✓ Reduction of non saleable batches, NPI and tech-transfer trials

- ✓ Reduction in manufacturing doc creation time, review and testing
- ✓ Cycle time improvements
- ✓ Improvement due to cross-site cycle time benchmarking

Operation Management Team and S88, Steps of implementation Projects

*We support **project assessment and implementation phases**, following a structured **scientific / academic methodology** to guarantee project success.*

1. Scope & Areas of Application Definition	Definition of project boundaries Identification of ISA 88 applicable areas Definition of business requirements
2. Process/Systems Analysis & Mapping	Assessment and data gathering of Recipe Development Process flow, Standard procedures, Documentation and system-application landscape
3. Gap analysis and Road map definition	Priority identification and gap analysis Definition of deployment & rollout plans Definition of evaluation metrics for implementation
4. Support to project execution*	Redefinition of process flows, SOPs and S88 guidelines Development of library and recipe templates Support to pilot initiatives and full implementations

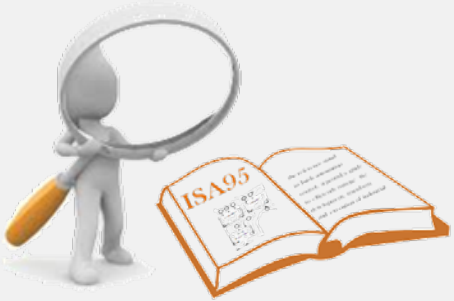
* Project Execution may vary based on the final project objectives

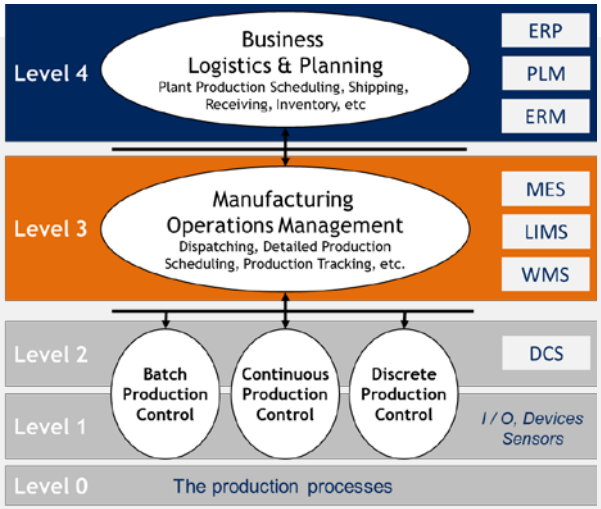
Strategic importance of managing integration and data exchange between business and manufacturing system and activities

1. Communication between business and manufacturing functions often lacks a common language
2. Missing of common ground knowledge among IT and Operations domain regarding fields of competence
3. Lack of harmonization of duplicate and/or overlapping processes
4. Difficulties in handling cross-domain project where different functions are involved

S95, What is it

*"S95 (short for ANSI/ISA-95) is the reference standard in batch automation and control, it provides guideline to efficiently define and manage information exchange **between business and manufacturing control systems**"*

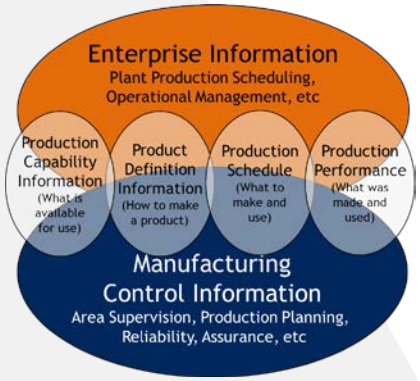




Functional Hierarchy Model

Production Operations Mgmt. Model

Part 1	Models and Terminology
Part 2	Object Model Attributes
Part 3	Activity Models of Manufacturing Operations Management
Part 4	Objects and attributes for MOM integration
Part 5	Business-to-Manufacturing Transactions
Part 6	Messaging Service Model
Part 7	Alias Service Model



Information Exchange Model

S95, What does it do

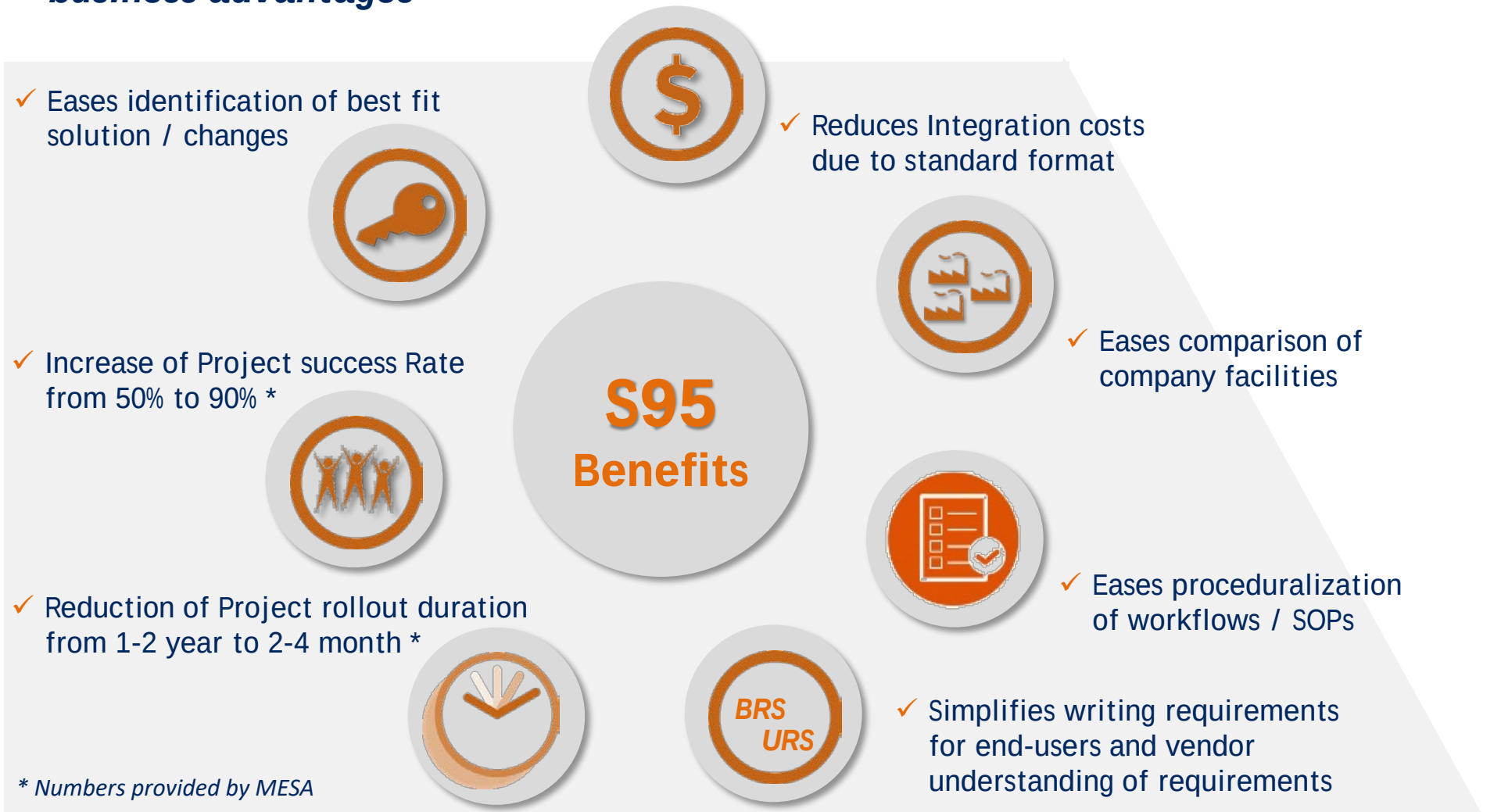
*"S95 brings a **company-wide perspective to system integration** that allows you to take thousands of actions and data points and boil them down to an understandable framework."*

Dave Gehman, Contributing Editor Automation World

1. Provides a reference model to define and integrate **business and manufacturing** activities
2. **Closes the gap** between business automation and process automation
3. Eases assessment and evaluation of **requirements for implementation** of new system solutions in the MOM area
4. Enables cross-functional alignment on **terminology and methodology**
5. Provides comprehensive **categorization** of manufacturing functionalities

S95, Benefits

*Applying S95 to the standardization of information exchange, during integration projects between ERP and MES/MOM area, guarantees both **technical** and **business advantages***



- ✓ Eases identification of best fit solution / changes
- ✓ Reduces Integration costs due to standard format
- ✓ Increase of Project success Rate from 50% to 90% *
- ✓ Eases comparison of company facilities
- ✓ Reduction of Project rollout duration from 1-2 year to 2-4 month *
- ✓ Eases proceduralization of workflows / SOPs
- ✓ Simplifies writing requirements for end-users and vendor understanding of requirements

** Numbers provided by MESA*

Operation Management Team and S95, Steps for implementation Project in MOM

*We support **project assessment and implementation phases**, following a structured **scientific / academic methodology** to guarantee project success.*

1. Scope & Area of Application definition	Definition of project boundaries Identification of ISA 95 applicable areas Definition of business requirements
2. Process/Systems Analysis & Mapping	Assessment of the MOM landscape (Production, Maintenance, Quality, Inventory, Other) based on S95 hierarchy and activity models
3. Gap analysis and Road map definition	Priority identification and gap analysis Definition of deployment & rollout plans Definition of evaluation metrics for implementation
4. Support to project execution*	Support to the implementation of automation / integration strategies in the MOM area (MES, LIMS, WMS, BES, AM, other)

* Project Execution may vary based on the final project objectives

OM Team solutions

OM Team, based on the customer requirements for implementation projects, can offer ad-hoc solutions. Below are examples of ***accomplished activities during previous business cases***

- **Education in ANSI S88/95 standard terminology and models**
  - Training packages development
  - Training courses (academic / business approach)
- **Recipe Development Process assessment & Gap Analysis vs S88/S95 standard**
  - As-Is process Mapping (resources, flows, doc, systems & applications)
  - To-Be process definition, in order to meet S88 Standard requirements
- **Creation of library structure & Recipes Design**
  - Process and procedural element, and equipment entity design
  - *Recipe deign as Visio* PPC custom stencils development
  - General recipe document creation
- **Support for Enterprise Recipe Management Systems Implementation & automation Projects (process work stream)**
- **Definition of investment plans and execution models**
  - Requirements for new system & process implementation (S88-S95 based)
  - Roadmap & Project plans definition

References

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References:
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