Manufacturing Hygiene

What can the personal care industry learn from decades of work in the food industry?

3-A Sanitary Standards, Inc.

March 22, 2022

Manufacturing Hygiene
What can the personal care industry learn from decades of work in the food industry?

- Part 1: Intro to 3-A SSI
- Part 2: Holistic Approach to Hygienic Design
- Part 3: 3-A Standards for API Equipment

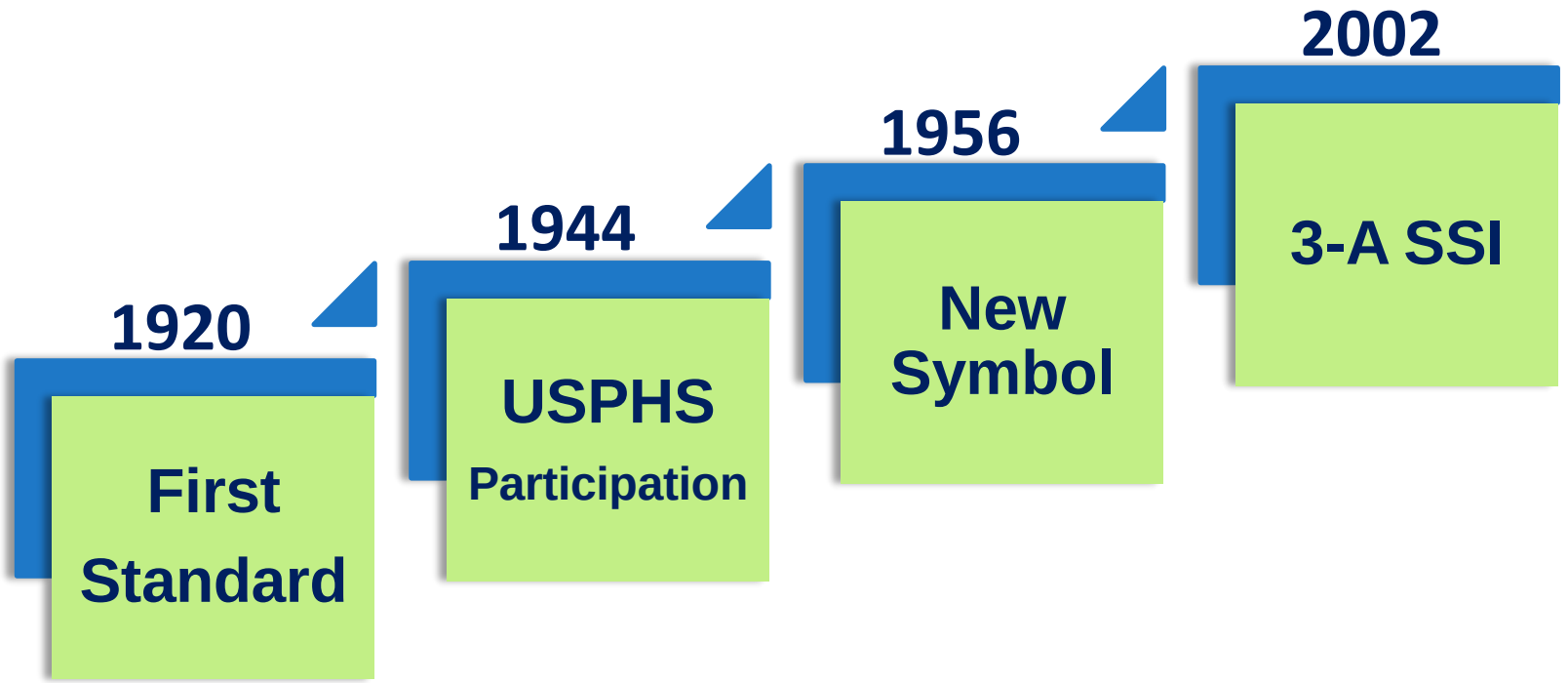
Mission

Enhance product safety for consumers of food, beverages, and pharmaceutical products through the development and use of 3-A Sanitary Standards and 3-A Accepted Practices.

Stakeholders in 3-A SSI

- Equipment Fabricators
- Regulatory Sanitarians/Consumers
- Processors

Brief History of 3-A SSI



3-A Sanitary Standards, Inc.

FPSA

IDFA International Dairy Foods Association

International Association for Food Protection

Before 2002

- FPSA Standards Writing
- IAFP Publishing
- 3-A Symbol Council

3-A Sanitary Standards, Inc.

- **Standards Writing & Publishing**
- **3-A Symbol Program Management**
- **Third Party Verification**
- **Training-Education-Harmonization**

Driving Forces for 3-A SSI

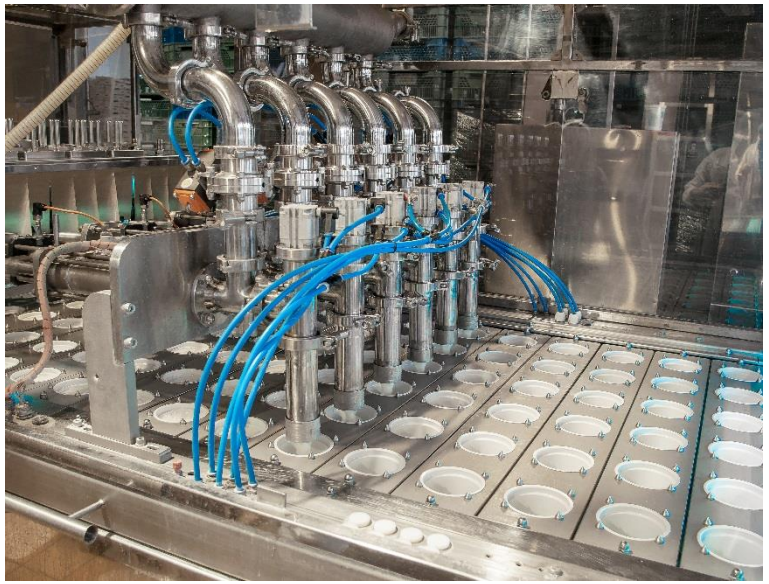
- Modernize consensus process
- Restore integrity of 3-A Symbol
- Develop authoritative knowledge resources and training
- Expand recognition and demand for hygienic equipment and 3-A criteria

Value of 3-A Criteria

- Modernize consensus process
- More efficient cleaning (saves labor)
- Fewer problems during inspections
- Universal acceptance by users & sanitarians
- More contributions to state-of-the-art design
- More sophisticated & consistent inspections
- More confidence in standards by sanitarians

What is a 3-A Sanitary Standard?

3-A Sanitary Standards specify the criteria for the design and fabrication of equipment that comes into contact with comestible products.



3-A Sanitary Standards

- Vessels
- Fillers
- Valves and Fittings
- Pumps and Mixers
- Heat Exchangers
- Conveyors and Feeders
- Instruments
- Concentrating Equipment
- Farm/Raw Milk
- Cheese and Butter Equipment
- Process and Cleaning Systems
- Plant Support Systems
- Materials and Materials Testing

What is a 3-A Accepted Practice?

3-A Accepted Practices specify the criteria for the design and operation of processes/systems that have a direct impact on the quality of comestible products.

3-A Accepted Practices

- Process and Cleaning Systems
  - HTST and HHST Pasteurizer Systems (603-)
  - Permanently Installed Product and Solution Pipelines and Cleaning Systems (605-)
  - CIP for Equipment (613-)
  - ESL/UP Practice (614-).
- Plant Support Systems
  - Air Under Pressure for Product Contact (604-)
  - Steam of Culinary Quality (609-)
  - Facilities Air Quality (612-)

About the 3-A Symbol

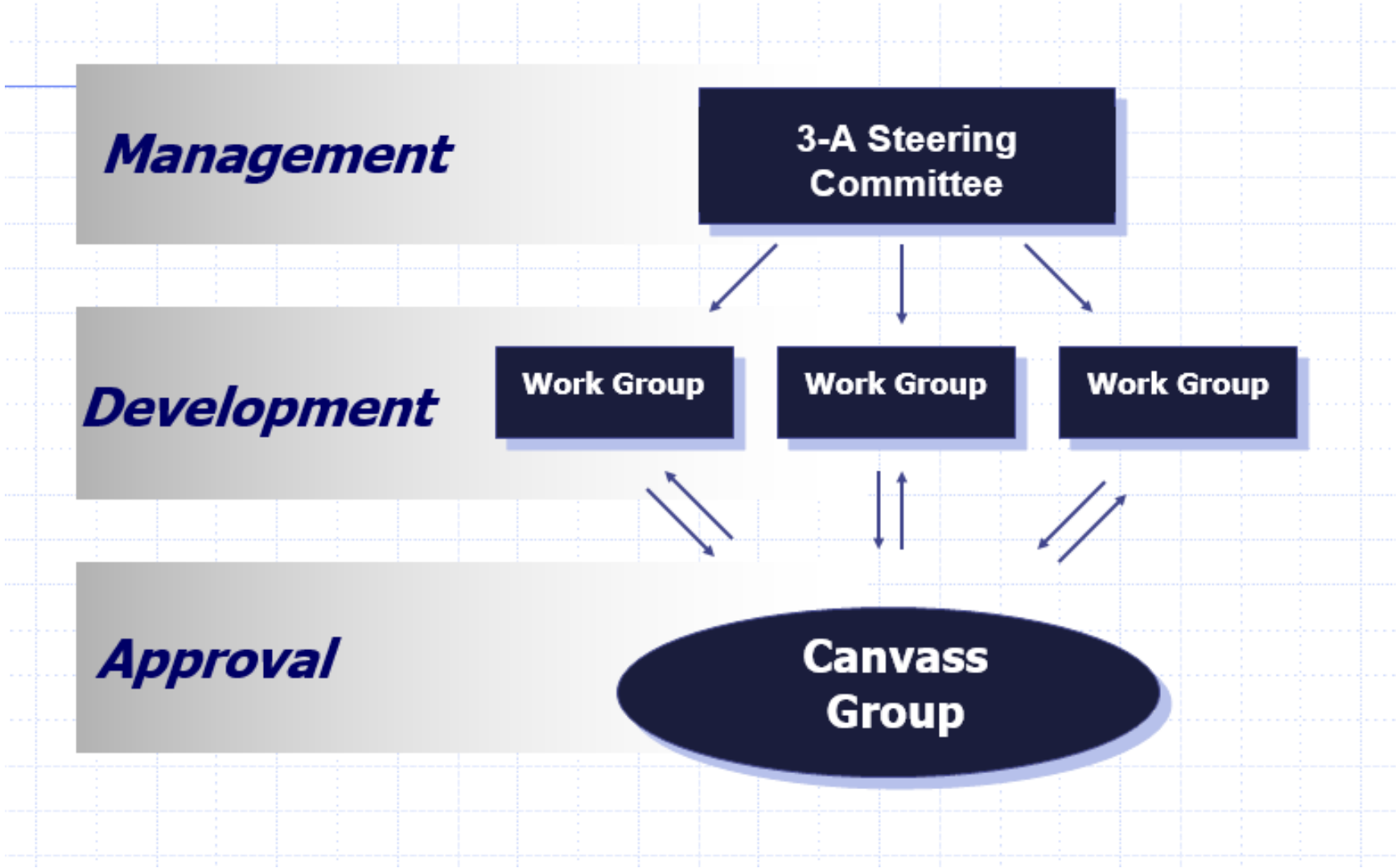
- Registered mark owned and licensed for use by 3-A SSI
- For use only on conforming, authorized equipment
- Requires evaluation of equipment by independent, credentialed authority – Certified Conformance Evaluator
- List of authorized users available at www.3-a.org
- Best way to verify authorized equipment

The Consensus Process

3-A SSI is an ANSI-accredited Standards Developer Organization (SDO)

- **3-A Sanitary Standards**
- **3-A Accepted Practices**

The Consensus Process



Holistic Approach to Hygienic Design

Manufacturing Hygiene for consumer products

Bryan Downer, Sani-Matic
3-A SSI Certified Conformance Evaluator

Holistic Approach to Hygienic Design

- → Regulations & Standards – The Role of 3-A
- → Equipment Design - Elements of 3-A Standards
- → Facility Design – Planning for Hygiene
- → Cleaning & Sanitizing – Methods & Processes
- → Operations & Quality – Assessment & Prevention

Holistic Approach to Hygienic Design

Value of Standardization

- Allows the use of standard equipment and methods
  - Standards & Accepted Practice
  - Reduce cost of re-engineering or over-engineering
- Provides for shared knowledge
  - Cleaning methods
  - Materials of construction
  - Harmonization of terminology
  - Regulatory acceptance
- Mitigates Risk
  - Proven and accepted methods
  - Verified suppliers and equipment

Equipment cGMP: 21 CFR, Part 117.40

- Very generic – one page
- Key points:
  - Cleanable
  - No allergen cross-contact
  - No contamination
  - Facilitates cleaning and maintenance
  - Corrosion-resistant PCS
  - Non-toxic
  - Withstand intended use and cleaning
  - Seams or joints are bonded
  - NPCS must be cleanable
- Standards like 3-A provide details of how to accomplish

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§117.40 Equipment and utensils.

(a)(1) All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and contamination.

(2) Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

(3) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.

(4) Food-contact surfaces must be corrosion-resistant when in contact with food.

(5) Food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.

(6) Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.

(c) Equipment that is in areas where food is manufactured, processed, packed, or held and that does not come into contact with food must be so constructed that it can be kept in a clean and sanitary condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature- measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be accurate and precise and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives.

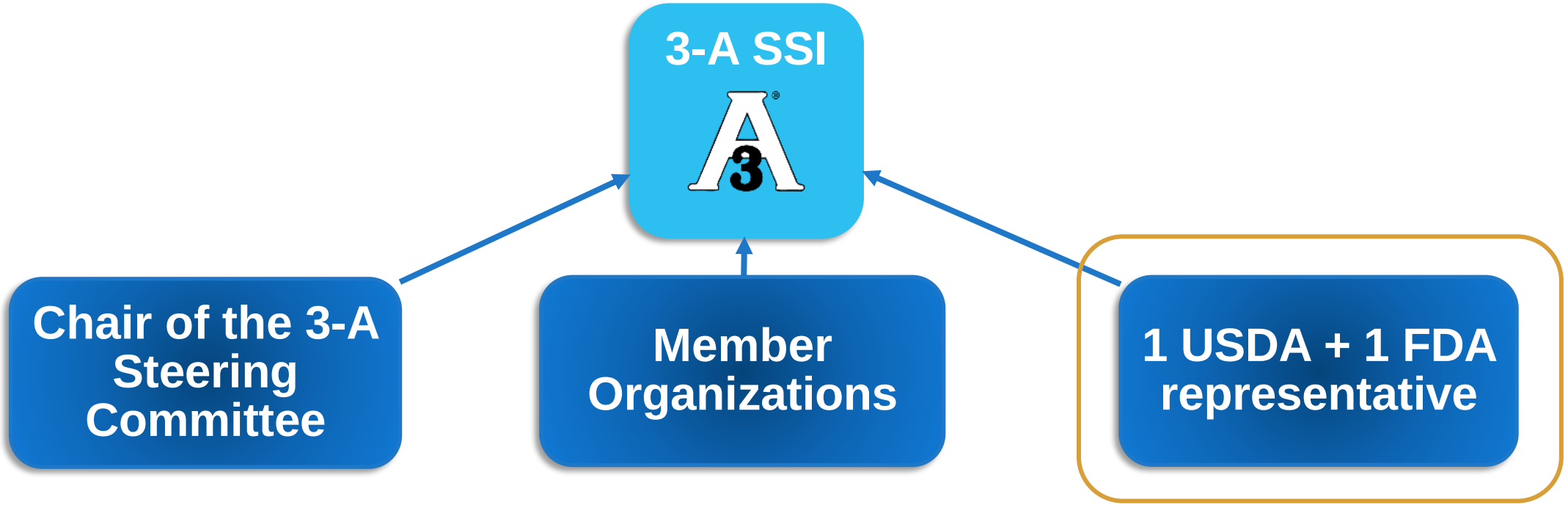
3-A Standards and Accepted Practices

- Vessels
- Fillers
- **80+ Standards & Accepted Practices**
- Valves & Fittings
- Pumps & Mixers
- Heat Exchangers
- Conveyors & Feeders
- Instruments
- Concentrating Equipment
- Raw Ingredients
- General Req'ments
- Process & Cleaning Systems
- Plant Support Systems
- Materials & Materials Testing

Hygienic Design Providers

ORGANIZATIONS	STANDARDS/GUIDELINES
3-A SSI (Sanitary Standards, Inc.)	Food Equipment Standards and Practices
EHEDG (European Hygienic Engineering & Design Group)	Hygienic Design and Testing Guidelines
NSF International	Hygienic Food Service Equipment Standards
AMI (American Meat Institute)	Ten Principles of Sanitary Design
BISSC (Baking Industry Sanitary Standards Committee)	Sanitary Baking Equipment Standards
ASME – BPE (Bioprocessing Engineering)	Hygienic Bio-Pharmaceutical Guidelines

3-A Sanitary Standards, Inc.



FPSA

IDFA
International
Dairy Foods Association

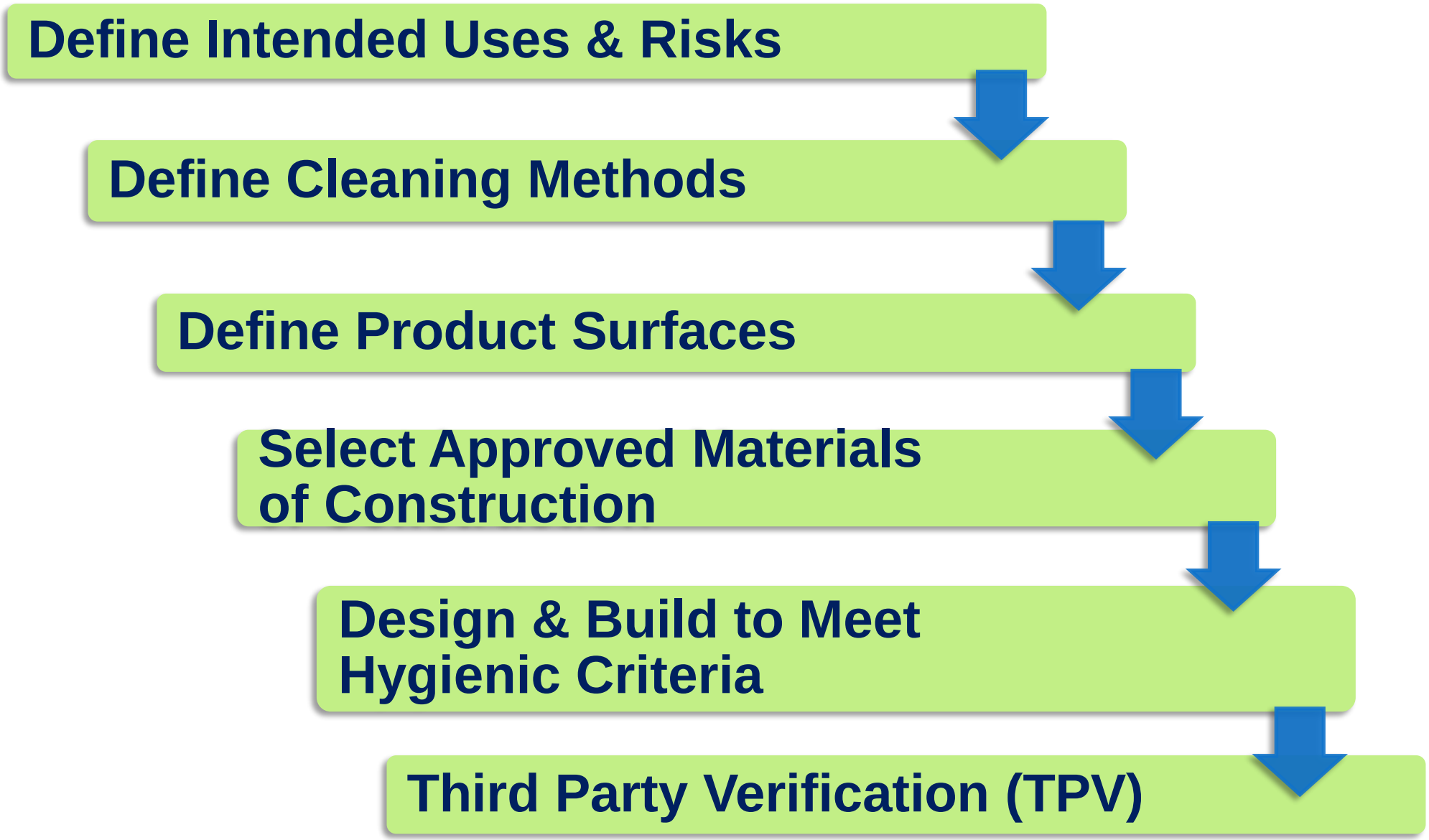
International Association for
Food Protection

Holistic Approach to Hygienic Design

Benefits of Hygienic Design

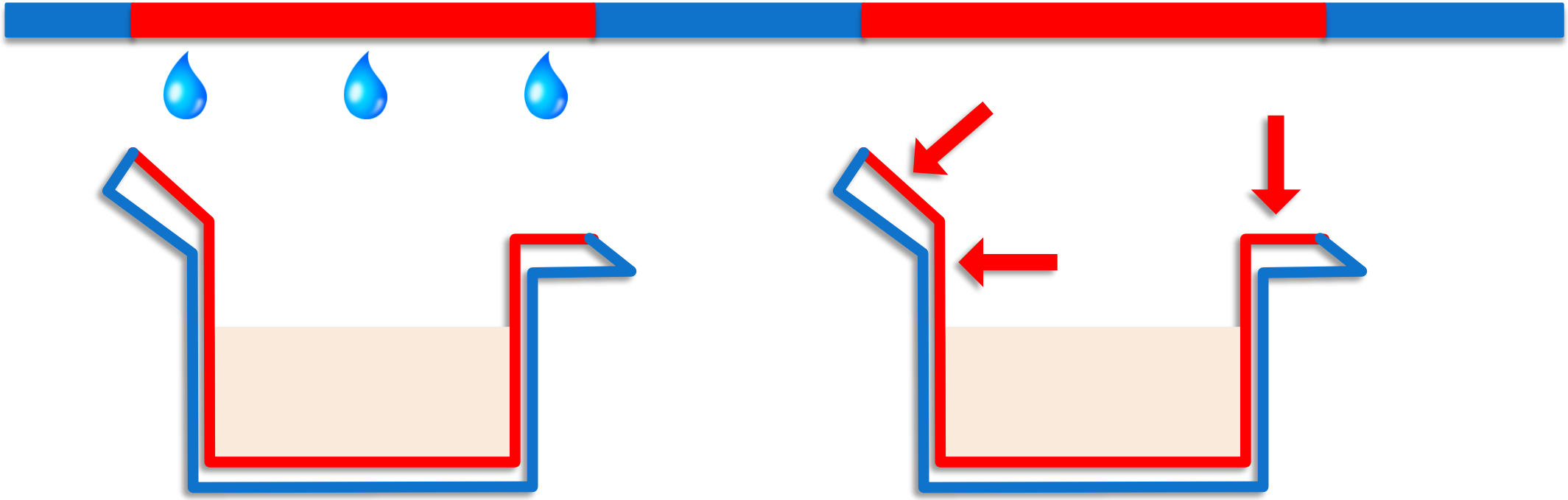
- → Improved Operational Equipment Efficiency
- → Reduce time and labor in cleaning and sanitizing
- → Increase production throughput
- → Reduce risk to consumer
- → Improves the product quality
- → Allows for cleaning to the microbiological level
- → Improves allergen control

Hygienic Design Process for Equipment

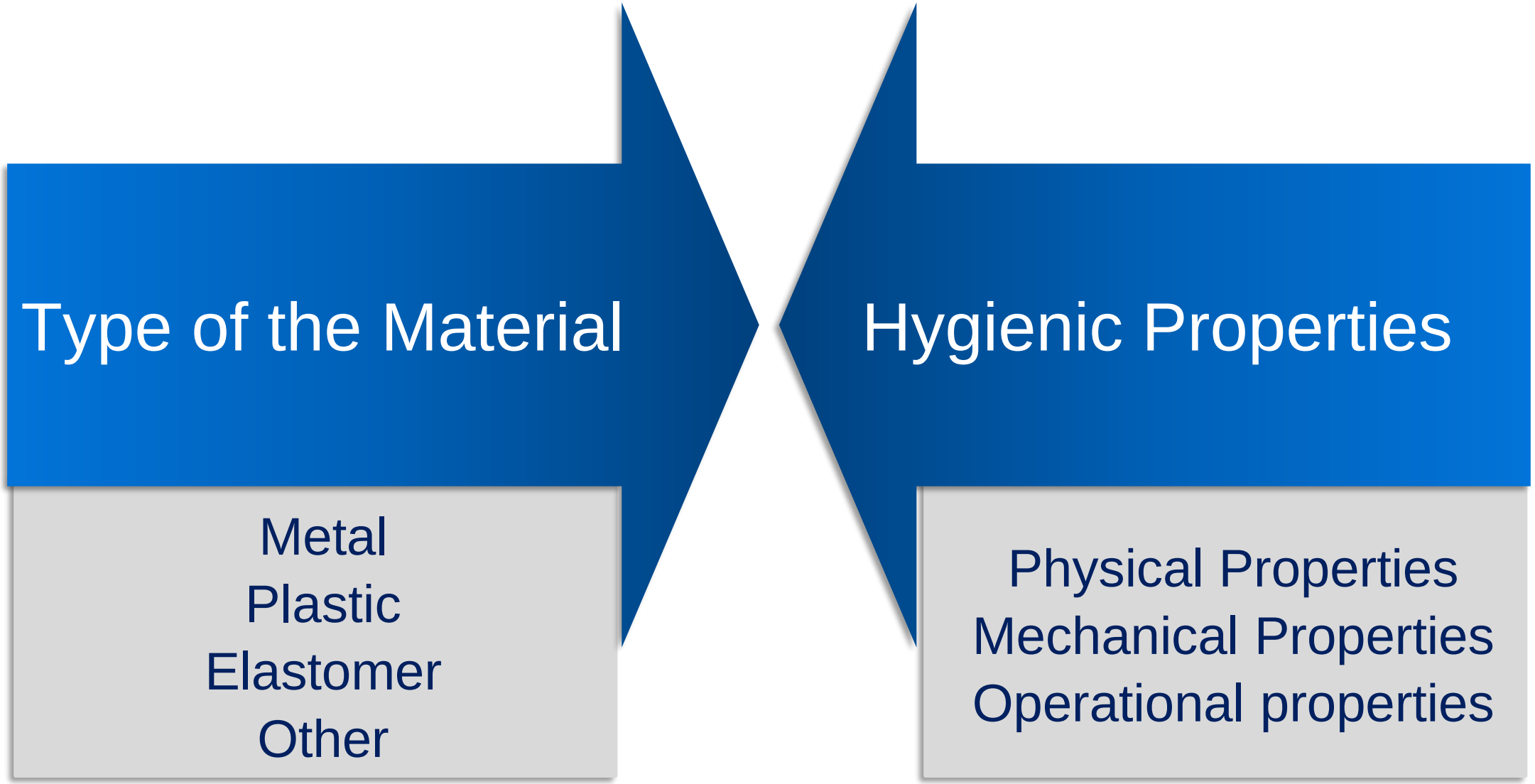


Product Contact Surfaces (PCS)

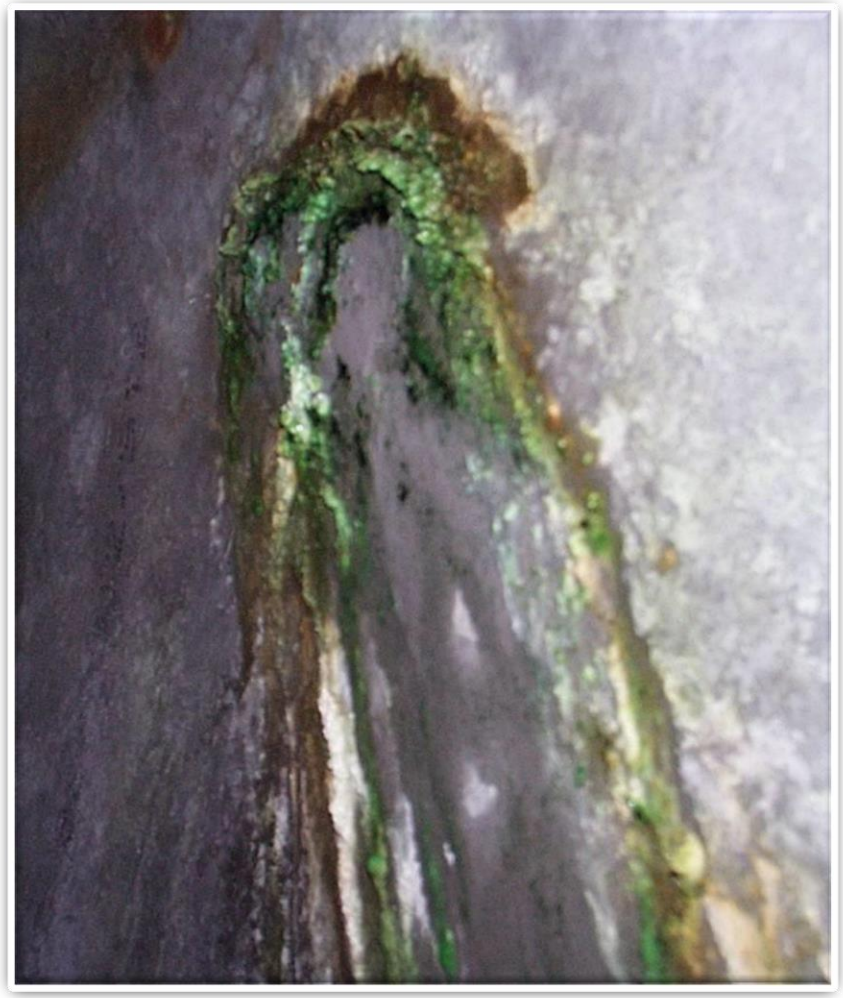
All surfaces which are exposed to the product and from which splashed product, liquids, or soil may drain, drop, diffuse or be drawn into the product or onto surfaces that come into contact with product surfaces of packaging materials

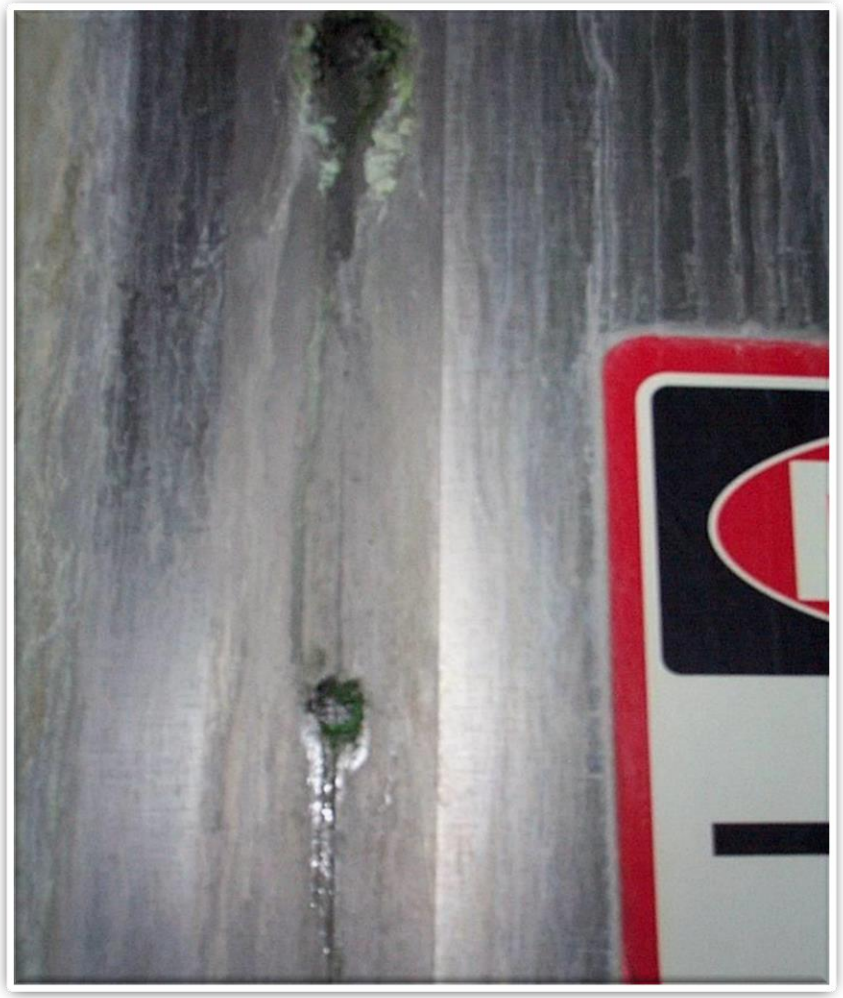


Select Approved Materials of Construction



Hygienic Risk Caused by Corrosion Failure





Rubber Failure:

- → Compression Set
- → Chemical Attack
- → Swelling
- → Gap Extrusion
- → Ozonolysis or Oxidation
- → Heat Ageing
- → Over Compression

Credit: Gabe Miller

Requirements to Welded Joints

- Continuously welded
- Meet surface finish requirements
- Meets Criteria of AWS D18.1, D18.2, and D18.3

- Not Acceptable

Hygienic Equipment Design Criteria

CLEANABLE

ACCESSIBLE TO CLEAN

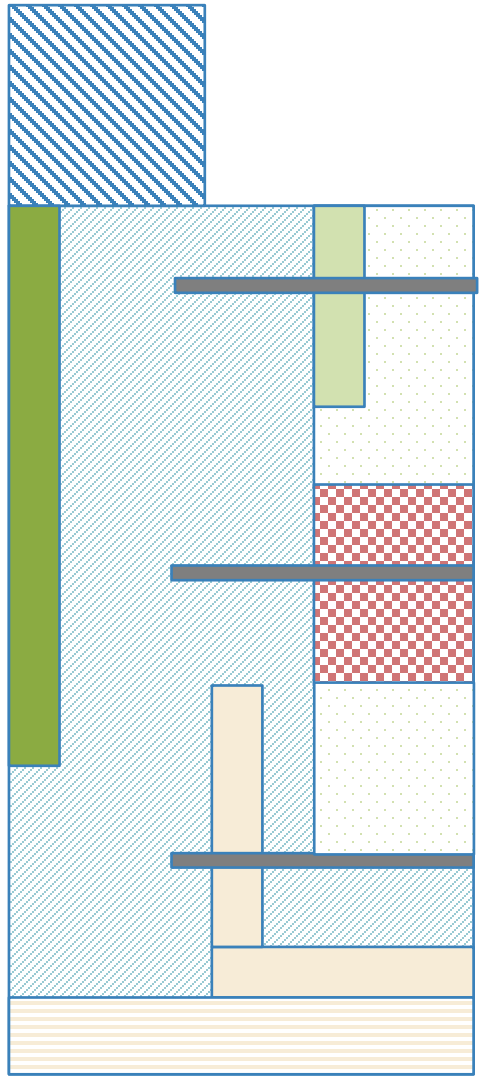
ACCESSIBLE TO INSPECT

- Cleaning Methods
- Types of Surfaces
- Materials of Construction
- Surface Finishes
- Joint Design
- Radii
- Free Draining
- Other Design Specifications

Holistic Approach to Hygienic Design

Facility Design & 3-A

- Process Flow
- Traffic Patterns
- Air Quality and Flow
- Area Classifications
- Materials of Construction
- Utilities & Access
- Grounds & Pest Control
- Security & Access



Standards allow adoption of standardized methods

Facility-Based Environmental 3-A Practices

#604 Supplying Air Under Pressure in Contact PCS

#610 Method of Producing Steam of Culinary Quality

#612 Plant Environmental Air Quality

Facility-Based Process 3-A Practices

- **#603** HTST Systems
- **#605** CIP & Piping Systems
- **#607** Spray Drying Systems
- **#608** Instantizing Systems
- **#610** Cross-Flow Membrane Systems

Holistic Approach to Hygienic Design

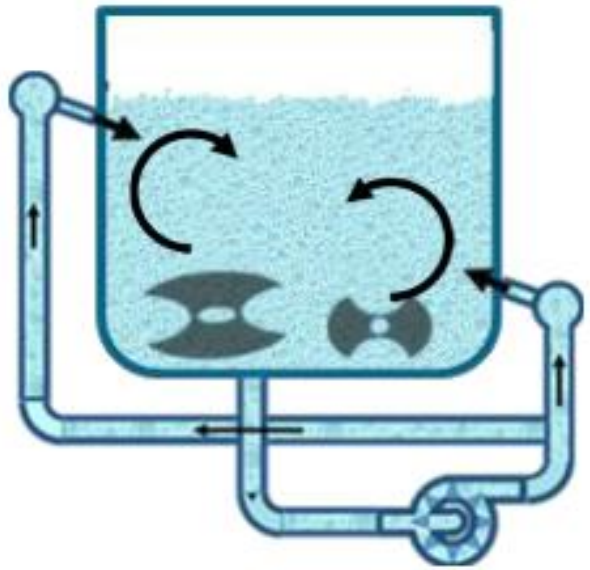
Cleaning Methods

Manual Cleaning

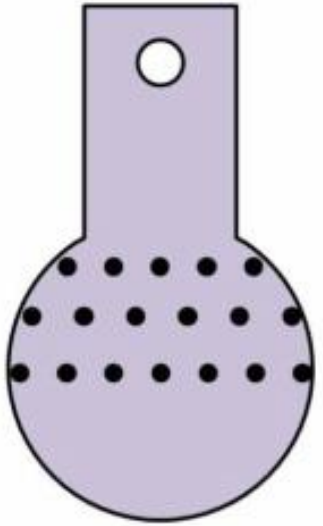
Wet

Dry

COP Cleaning



CIP Cleaning



Cleaning Methods

Improving Efficiency and Efficacy

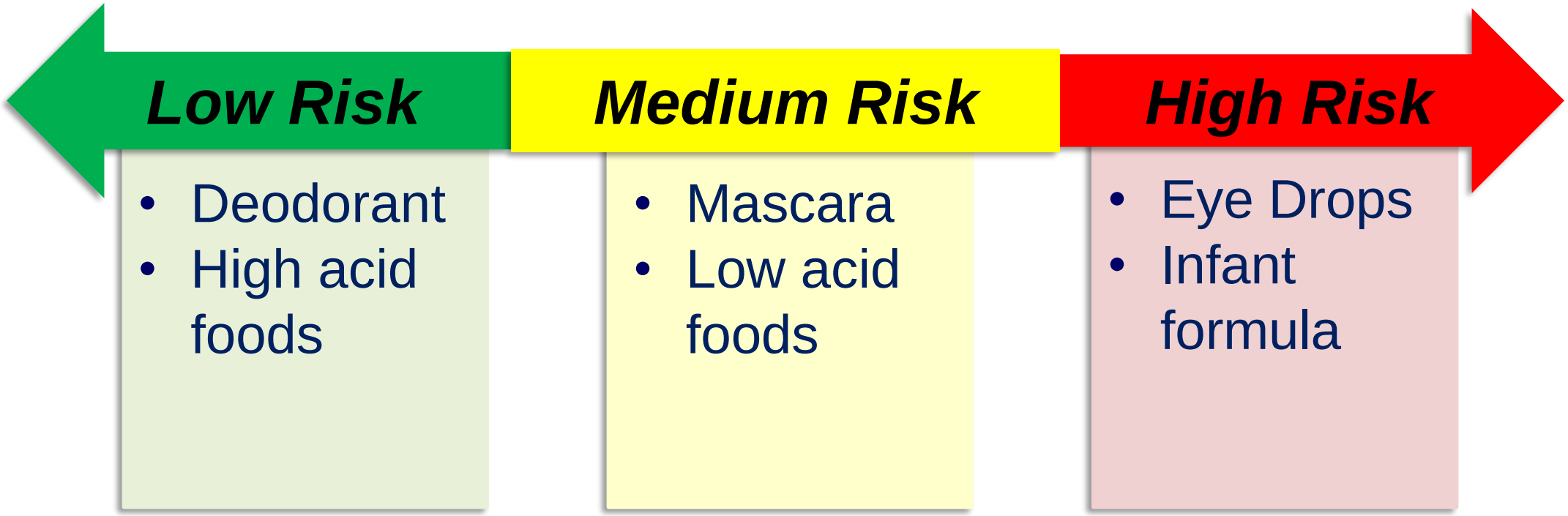
Cleaning Method	Time	Action	Chemistry / Concentration	Temperature
Manual	H	H	H	H
COP	L	H/L	L	L
CIP	L	L	L	L

H = High Risk **L = Low Risk**

Standards allow adoption of standardized methods

Intended Application and Risks

Applying appropriate mitigation methods



Process Type Risks

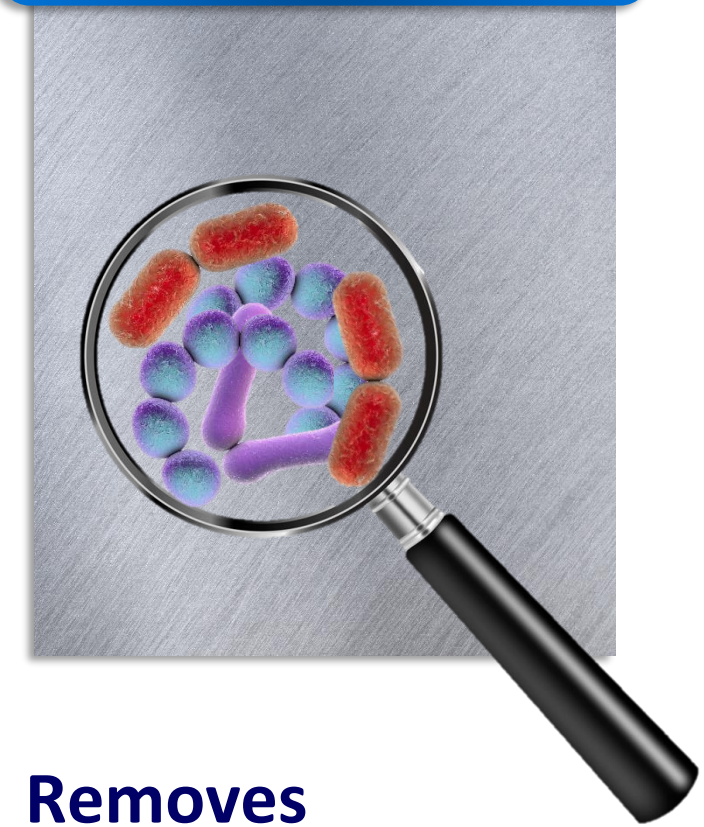
Applying appropriate mitigation methods

Consumer Risks

Applying appropriate mitigation methods

Cleaning vs. Sanitizing vs. Sterilization

CLEANING

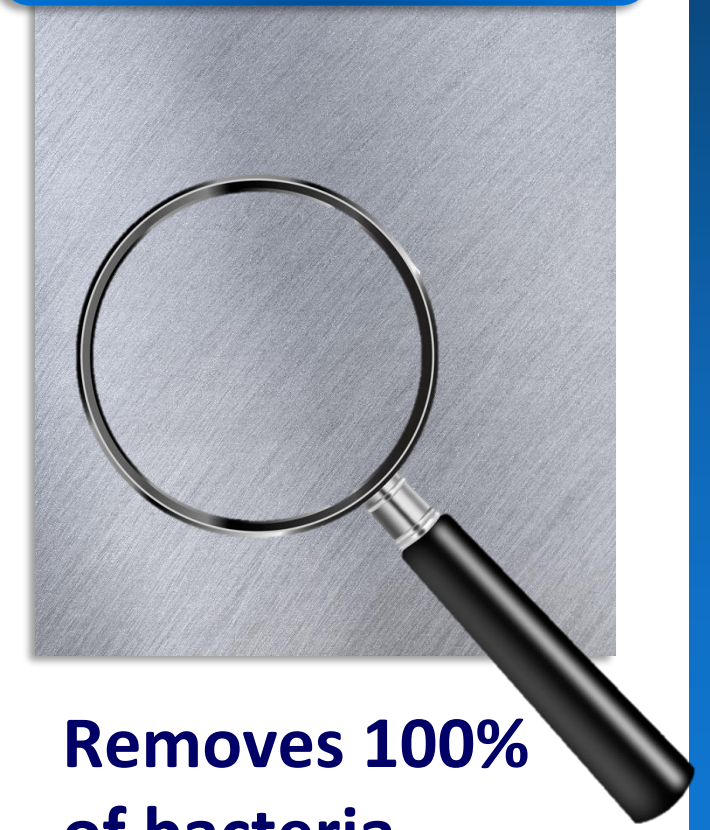


Removes Product/Soil

SANITIZING

Removes 99.999% of bacteria

STERILIZATION



Removes 100% of bacteria

Holistic Approach to Hygienic Design

Operation & Quality

Sanitary Operations

Equipment & Utensils

Personnel

Processes & Controls

Holding & Distribution

Sanitary Facilities & Controls

Warehousing & Distribution

Plants & Grounds

Defect Action Level

Operation & Quality

Written Quality Programs: Required for Both Equipment Fabricators and Processors

- Program scope & organization
- Management responsibility
- Documentation
  - Quality Manual
  - SOP documents
  - Change Control
- Training plans
- Records of quality activities
- Corrective actions
- Preventive actions
- Audits

Training & Technical Resources

Training
- 3-A Online training
- 3-A Annual Meeting
- Volunteer Involvement

Technical Resources
- Standards & Accepted Practices
- Connection to experts
- Community

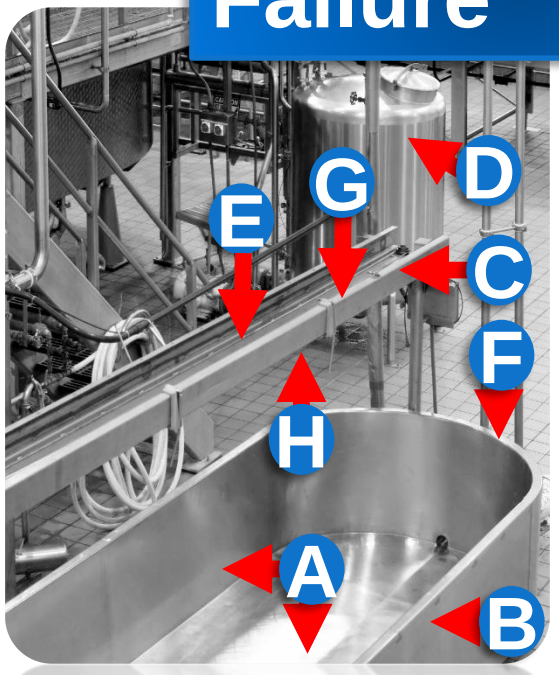
Standards allow adoption of standardized methods

Training

Corrosion

Environmental Failure

- Heat
- Pollution
- UV rays



- → **Electropolishing**
  - → Reverse plating – removes metal to improve surface finish
- → **Passivation**
  - → Chemical process to restore chromium and nickel oxide layer on stainless steel,
  - → Removes iron contamination from manufacturing process
  - → Passivate after field renovations

3-A Standards for API Equipment

A Case Overview

3-A Sanitary Standards, Inc.

March 22, 2022

Case Study
Pharma P3-A Standards

The Origins of P3-A

- Increased scrutiny on API Manufacturing in recent years drove the need for Cleaning Validation of API Equipment.
- It is costly for each company to have API equipment manufacturers make specific changes to make equipment easier to clean – is there a consensus on required changes?

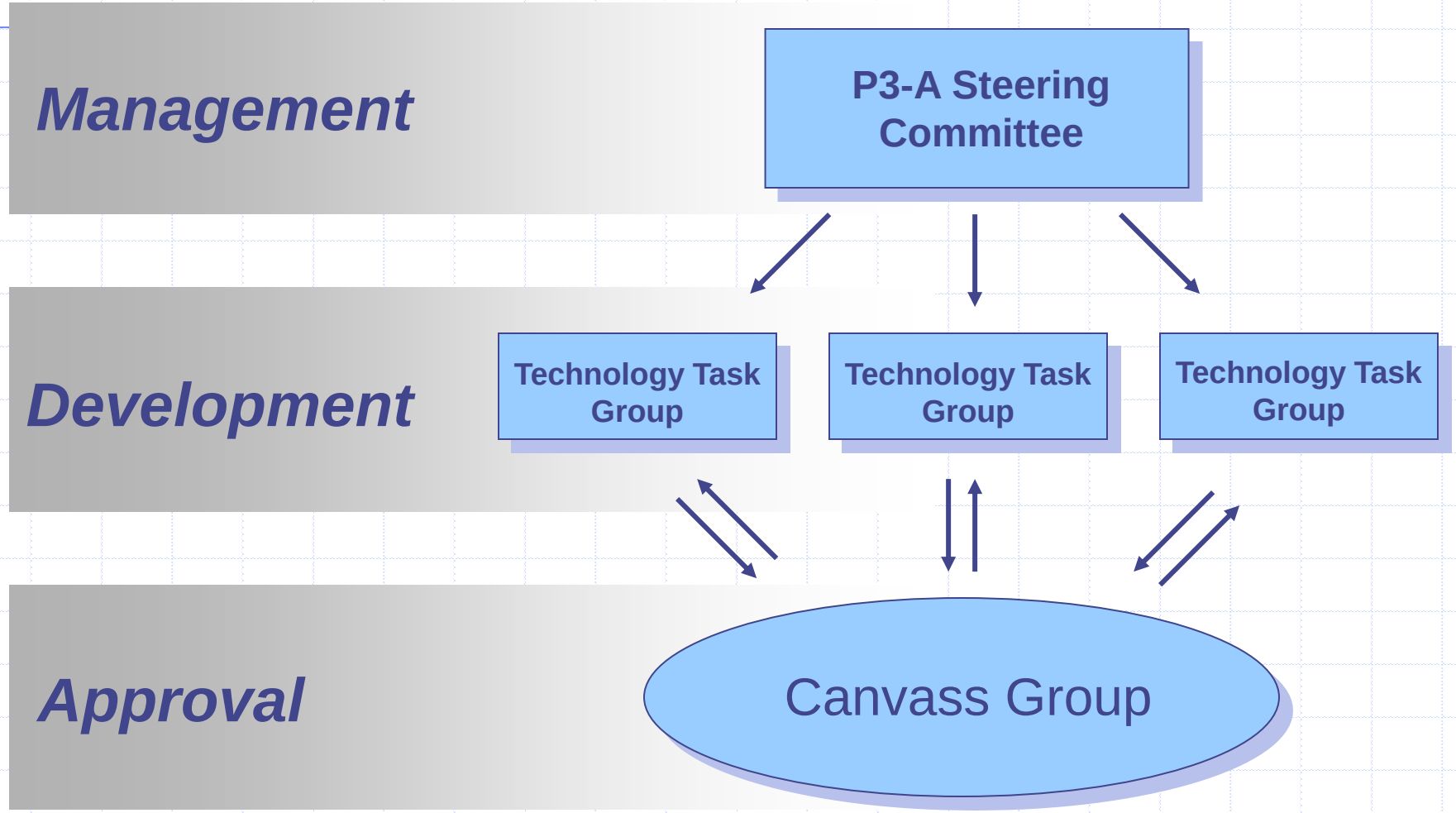
The Origins of P3-A

- No suitable industry standards existed for the design of cleanable API Equipment.
- The Existing 3-A Standards (dairy) were not suitable for most API Equipment.
- The ASME BPE Standards were not suitable for many types on API Equipment.

The Origins of P3-A

- Existing benchmarking effort among several API manufacturers was expanded to include the development of Standards for Cleanable Design of API equipment.
- Started working with 3-A SSI as the umbrella organization for the Standards development.

Organizational Structure - Overview



P3-A Steering Committee

Project Plan/Approach

"Begin with the end in mind"

Three Stages

Follow the Pharmaceutical Process Schema

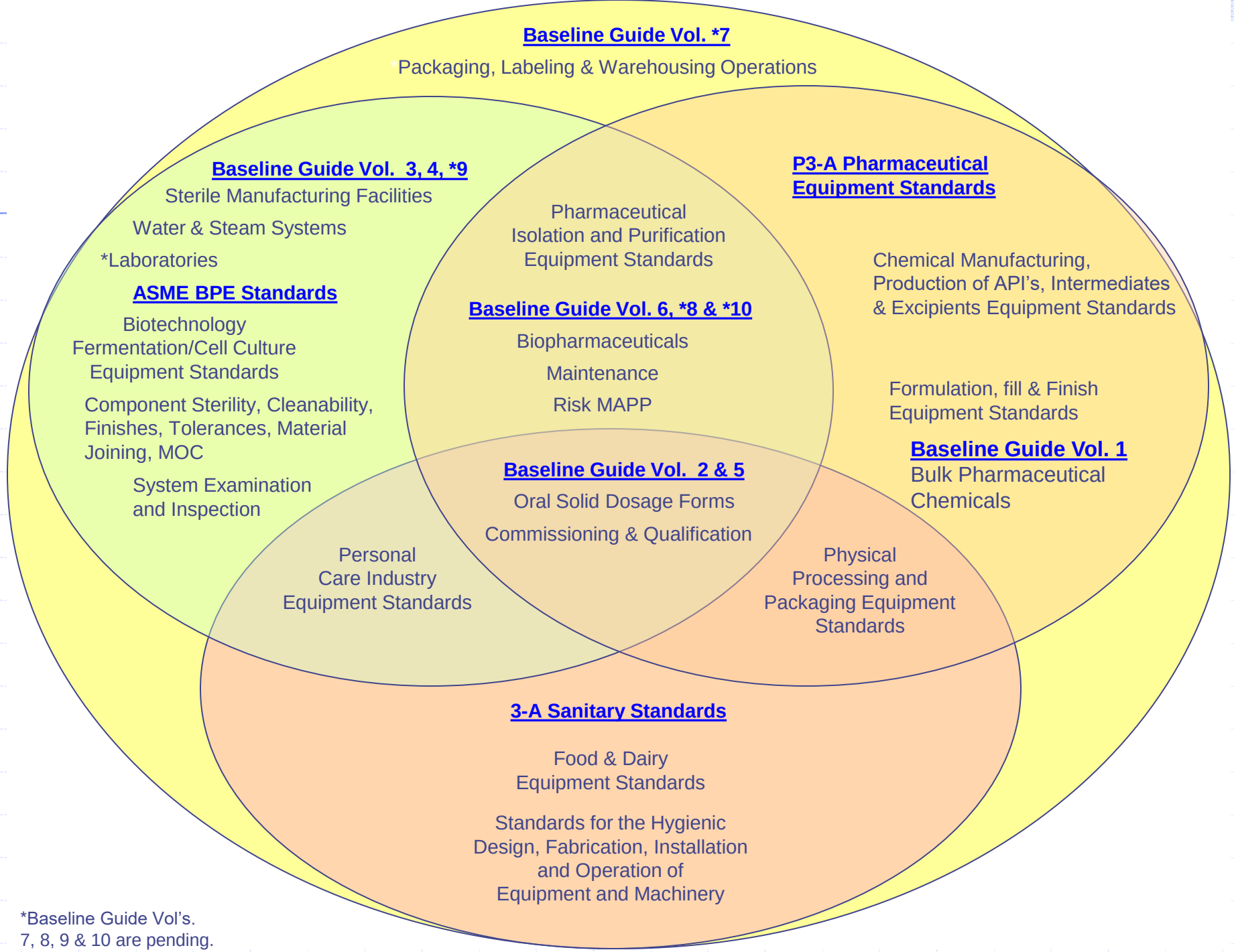
- **Active Pharmaceutical Ingredient (API) synthesis/isolation**
- **API conversion to dosage form**
- **Final Packaging**

P3-A Steering Committee

- **API Production**
  - Synthetic chemistry
  - Fermentation
  - Isolation/sizing

  → Containment
  - Limited equipment sets – easier to standardize
- **Dosage forms**
  - Tablet or capsule
  - Liquid solution or suspension
  - Semi-solids (cream, ointment, gel)
  - Sterile ophthalmic
  - Sterile Injectable
  - Inhaled powders

The future holds great promise



*Baseline Guide Vol's. 7, 8, 9 & 10 are pending.

The Scope of P3-A Standards

- In general, chemical pharmaceutical manufacturing involving small molecule manufacturing and purification
- These processes are usually solvent based, with highly acidic or basic pH conditions that inhibit microbial growth and contamination.
- Sterile and aseptic design is less critical.

The Business Case

- Lower cost of Standards development by using 3-A Dairy Standards as the starting point. There are 52 related equipment types, with cleanability and sanitary design requirements already included.
- Decrease in equipment costs when vendors build to a single standard.
- Decrease in capital project specification time and costs by having a strong starting point for the process. Increased compliance with sanitary codes and principles, including internal Quality Standards.

The Business Case

- Presentation of a “unified front” within the pharmaceutical industries will assure the compliance and cooperation of equipment vendors.
- 3-A SSI already has working relationships with the FDA, USDA, and other regulatory agencies.
- 3-A SSI’s Third Party Verification program will enhance acceptance by inspection authorities.
- American National Standards (ANSI) applied across site locations.

New P3-A Standards

P3-A-001 TERMINOLOGY

ANSI/3-A P3-A 001-2008
General Glossary of Terminology Used in Pharmaceutical 3-A® Standards

FINAL BSR ACTION – Published March 7, 2008

P3-A-002 MATERIALS

ANSI/3-A P3-A 002-2008 Pharmaceutical 3-A® Sanitary/Hygienic Standards for Materials for Use in Process Equipment and Systems

FINAL BSR ACTION – Published February 29, 2008

P3-A-003 PUMPS

ANSI/3-A P3-A 003-2008 Pharmaceutical 3-A® End Suction Centrifugal Pumps for Active Pharmaceutical Ingredients

FINAL BSR ACTION – Published August 1, 2008

P3-A-003 PUMPS

PROVIDES PUMP PROCUREMENT & DESIGN GUIDANCE

P3-A Centrifugal Pump Data Sheet

*SERIAL NUMBER: _____

1	**GENERAL INFORMATION**	**MATERIALS**
2	SERVICE:	CASING:
3		IMPELLER:
4	DUTY: CONTINUOUS INTERMITTENT	SHAFT: SHAFT SLEEVE:
5	(PLEASE CIRCLE ONE)	MOUNTING BASE (MATERIALS):
6		PRODUCT CONTACT SURFACE FINISH (R/ µin Ra (1.6 µm Ra)
7	**PROCESS INFORMATION**	GASKETS:
8	LIQUID:	O-RINGS:
9	BOILING TOXIC FOAMING FLAMMABLE	**CONSTRUCTION**
10	DESIGN FLOW: MIN NORMAL MAX GPM	SIZE / RATING / (CIRCLE)
11	PUMPING TEMP. RANGE (PROCESS): °F	*SUCTION CONNECTION ____ ____ RF FF
12	SP. GR. @ PUMPING TEMP.:	*DISCHARGE CONNECTION ____ ____ RF FF
13	VISC. @ PUMPING TEMP.: CPS	DRAIN CONN.: (1/2" STANDARD)
14	VAPOR PRESS. @ PUMPING TEMP.: (PSIA)(mmHg)	
15	CORROSIVE MAT'L: pH VALUE:	*CASING DESIGN PRESSURE: PSIG @ °F
16	SOLIDS (MAX. DIAM.): % BY WEIGHT:	
17	CIP/SIP: (PLEASE CIRCLE ONE)	*IMPELLER SIZE: MAX:
18	ABRASIVE NON-ABRASIVE	
19	(PLEASE CIRCLE ONE)	MATERIAL CERTS REQUIRED: YES NO
20	**HYDRAULIC INFORMATION** / FT. LIQ.	MATERIALS CERTIFICATES OF CONFORMANCE: YES NO
21	SUCTION PRESS. ABOVE LIQ. (ABS)(+)	
22	STATIC SUCTION LIFT (-) HEAD (+)	COOLING/HEATING/PIPING PLAN:
23	SUCTION FRICTION (-)	
24	TOTAL SUCTION HEAD (21+22+23)	BEARINGS: TYPE G.F.L. GREASE: (ZERK) OIL FLOOD
25	STATIC DISCHARGE HEAD (+)	*BEARING MFG I.D. NO: THRUST RADIAL
26	DISCHARGE FRICTION HEAD (+)	
27	DISCHARGE PRESS. ABOVE LIQ. (ABS)(+)	BASEPLATE: MFG STANDARD OTHER
28	TOTAL DISCHARGE HEAD (25+26+27)	
29	TOTAL DYNAMIC HEAD (28-24)	*WEIGHT: PUMP BASE MOTOR
30	NPSH AVAILABLE	**DRIVE**
31	*NPSH REQ'D NORMAL MAX	FURNISHED BY: VENDOR OTHER
32	*SEAL CHAMBER PRESSURE	TYPE:
33	**PUMP**	MANUFACTURER:
34	*MANUFACTURER:	ENCLOSURE: INSUL:
35	*MODEL: CURVE RPM:	Hp: RPM: FRAME:
36	*BHP @ SERVICE CONDITIONS:	VOLTS: PHASE: CYCLE:
37	*BHP @ MAX FLOW FOR IMPELLER (N.O.L.):	*BEARING MFG I.D. NO: FRONT REAR
38		LUBRICATION:
39	*PERF. CURVE: PSIG	COUPLING TYPE: OSHA GUARD:
40	*SERIAL NO.:	COUPLING MFG: MODEL:
41	*NOTES:	
42		

* VENDOR TO SUPPLY INFORMATION WITH QUOTATION

The P3-A Symbol

QUESTIONS?