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Hygienic food production using a holistic approach

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DTU Nanotech
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Concurrent approaches of hygienic design


- Top down
 - Specify and design a plant
 - Design and validate the prospective application
 - Break down into manageable parts = lines / units / modules
- Bottom up
 - Use hygienic design rules and guidelines to design equipment
 - Use guidelines to assemble a hygienic processing line and construct the entire plant
- Concurrent top down / bottom up
 - Specify the level of protection
 - Design the cleaning routines



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Levels of hygienic design - 1 (Factory)


- The processing plant
 - Outside area - surroundings
 - Installations, power, drain and water supply
 - Building and building-material
 - Accommodation in general - different zone (prevent of cross contamination)
 - Installation of equipment
 - Restricted admission
 - Ventilation



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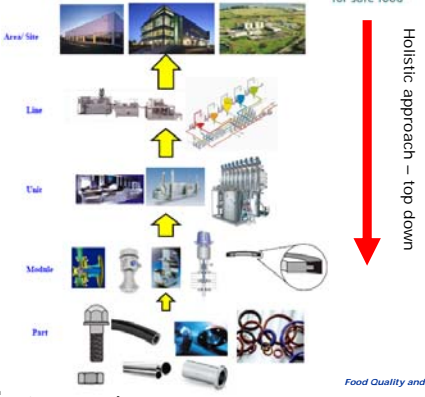
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Levels of hygienic design - 2 (Line / module)



- Production line
 - Make sure cleaning is possible
 - Production procedure
 - Product flow and flow of cleaning material and equipment
 - Correct connections of different types of material and parts
- Processing equipment and there combinations
 - Form and design (drainable)
 - Secure that cleaning is possible
 - Flow parameters
 - Use of current guidelines

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Common approaches

- Identify the operations / units
- Analyse the specific operation and need for protection
- Design the entity
- Validate the entity
- Apply the solution
- Document each decision
 - The purpose of each entity and operation
 - Those applied
 - Those not used and why




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Holistic / top down approach


- Inherits much of it's nature from zoning
- Is a part of a total concept to prevent contamination
- Ask the questions:
 - What must be protected? From what? And exactly where?
- Identify the most well defined and appropriate area to address
- This requires
 - division in to areas having a well defined function and risk level
 - knowledge concerning product, process and handlings which leads to prevention
- Define the proper action
 - Build-in protection / cleaning / disinfection / etc




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The Master Plan


- Every plant shall have and updated master plan containing
 - all pipe connections
 - All access ways
 - All paths where product and / or personnel moves
- The plan must be review minimum every year
- Future planning must relate to the master plan
- A contamination of a product, may be much easier to track if all connections etc are known
- When a plant is changed the plan must change accordingly


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Integrated Approach to hygienic design

- What is an integrated approach to hygienic design?
 - systematic combination of hygienic entities into a hygienic facility
- The holistic approach is to maintain the original necessary focus on any decision and selected operation and integrate this
- This may be a new design or reassignment of existing **entities**
 - An **entity** is a component part of a hygienic system, and can be for example a part, an assembly, a module, a line, or a factory





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Integrated Approach to hygienic design

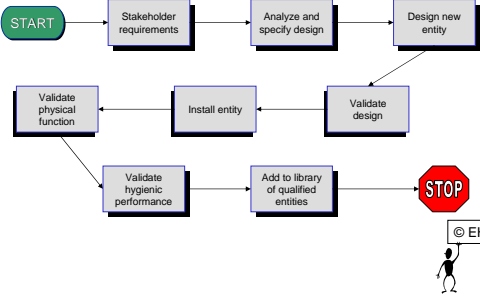
- Definition of "Hygienic Integration":
The process of combining or arranging two or more entities to work together while eliminating or minimizing hygiene risks.
- The integrated approach also includes specifications for product flow, control strategy, automation, maintenance, change management, training of personnel etc.






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A single integration step






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A single integration step

- At each integration action entities must have at least a prospective validation identifying probable failure modes
- Hygienic integration should be carried out on a modular basis, with entities that have passed the functional requirement for integration
- Instructions must cover: installation, operation, cleaning, sterilization (if applicable) and maintenance
- Concurrency with design and validation activities other than those concerned with hygiene is a prerequisite!






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Nomenclature – 1

- **Containment:** The total physical hygienic or aseptic boundary of a managed domain/zone, of a building, room, cabinet, or isolator
 - Can include transfer zones, differential air pressure systems and the seals, thermal barriers at physical penetrations for piping, light fittings, cables, ducts, vents and drains
- **Hygienic Maintenance:** The continual assurance of hygienic food production by replacement or adjustment of entities of a system *prior* to any hygiene failure
 - Replacement entities must be original parts, or have been validated to give satisfactory hygiene performance



 


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Nomenclature – 2

- **Design Change:** Any alteration of any hygienic entity within a food production system (*procedure, part, module, unit, process line, specification, formulation, personnel, building, document, etc.*), including any substitution where the hygienic entity is not replaced by an **exact** copy, potentially causing hazards to food safety or quality
- **Change Management:** A documented procedure in which all design changes are documented and reviewed by a multifunctional team. This team must use an HACCP or similar risk assessment study to manage safely any proposed or enforced alteration in parts of a food production hygienic system



 


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The relationship between the approaches

- Holistic approach / top down - First use
 - to specify the plant and operations
 - Make the prerequisite for integration
- Integration / bottom up
 - Design of plants following a specification
 - Builds on previous knowledge of good or best practices
- Holistic approach / top down – once in use
 - it helps keeping track of original decisions
 - Provides sense for each operation (cleaning / maintenance / etc)

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Thank you for listening ☺

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