

## Product Design and Development

*Controlling Product Design and Development to Manage Regulatory, Industry and Customer Risk*

### Development

*To define detail, scope and purpose.*

### Development

This information can be used to develop food safety and quality programs that meet the requirements of modern Regulatory, Customer and Industry Standards:

- We take the time to explain the expectations and requirements of food safety and quality compliance as these relate to your food safety and quality programs.
- You may choose to use our Premium Resources to build, enhance or upgrade your food safety and quality program.
- We encourage you to share this webpage with any food compliance associates and peers you believe may benefit from our commitment to providing our users with user-friendly information and resources to achieve superior Food Compliance Culture.
- We welcome your suggestions for additions of general or specific content through the haccp.com Contact Page.

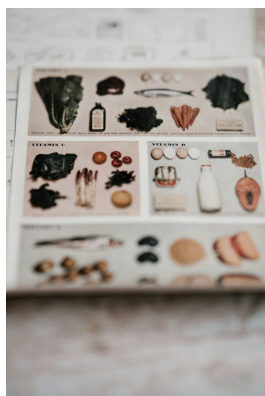
### Key Definitions for Product Design and Development

- **Challenge Testing:** Testing in which a product is deliberately inoculated with specified microorganisms, and their survival or growth is monitored, to confirm that the product can control them throughout its shelf life.
- **Claim:** A statement or representation about a food, such as a nutrition, health, ingredient, origin, or production claim, that must be accurate and able to be substantiated.
- **Design Review:** A documented review of a product design at a defined stage to confirm that it meets its requirements and to identify any problems.
- **Gate:** A point in the product design and development process at which a decision is made to proceed, hold, rework, or stop the project.
- **Gatekeepers:** The senior management team who make the decision to Proceed, Kill, Hold, or Rework a project at each gate.
- **Product Design:** Product design can be defined as the idea generation, concept development, testing and manufacturing or implementation of a physical object or service. Product designers conceptualise and evaluate ideas, making them tangible through products in a more systematic approach.
- **Product Development:** Commonly known as New Product Development or NPD, this is the term used to describe the complete process of bringing a new product or service to market.
- **Product Specification:** An explicit set of requirements to be satisfied by a product, including its ingredients, composition, process, packaging, labelling, and safety and quality parameters.
- **Prototype:** A prototype is an original type, form, or instance of something serving as a typical example, basis, or standard for other things of the same category.
- **Shelf Life:** The period during which a product remains safe and continues to meet its specified quality criteria when stored under nominated conditions.
- **Shelf Life Validation:** The process of gathering evidence, through testing and assessment, that a product remains safe and meets its quality criteria for the full nominated shelf life.

### Product Design and Development

When considering the development, documentation, and implementation of Product Design and Development within food safety and quality management systems, the following information should be considered to ensure effective outcomes:

## About Product Design and Development



*Product design begins with a clear understanding of ingredients and requirements.*

Procedures for product design and development must be developed, documented and implemented to ensure the process yields appropriate outcomes. The product design and development should include structured consideration of HACCP, production trials, specifications, packaging, labelling and shelf life consideration for microbiological, chemical, physical and organoleptic parameters including challenge testing where applicable.

Further information on regulatory requirements can be found within the haccp.com HACCP: Regulatory Hazards Management Food Standard Element.

It is important to consider within any Product Design and Development flow process that applications will need to be applied in a logical sequence. Each stage of the Product Design and Development process contains a set of prescribed and concurrent activities incorporating industry best practices. The activities during a stage are generally anticipated to be applied in parallel, not in sequence. This ensures that they are carried out quickly and effectively. Process stages must be cross-functional to allow all areas of the food business to contribute.

## The Gate Process



*Each gate is a documented decision point for senior management.*

For best outcomes, each stage of the Product Design and Development process following the idea stage can be preceded by a gate. Gates are the points in the process where a decision must be made. The gatekeepers can choose to Proceed, Kill, Hold, or Rework the project.

Gates are in effect quality control checkpoints which should highlight answers to the following questions:

- Has the previous stage been executed in a quality fashion?
- Has the project team completed its tasks appropriately?
- Is the project viable from an economic and business standpoint?
- Is the action plan suitable?

This is where project prioritisation and resource allocation decisions are made. At the end of a gate meeting, a decision must be reached. If the decision is to Proceed, this confirms resource commitments and support from management.

Gatekeepers are the team of senior management who make decisions to Proceed, Kill, Hold, or Rework the project at gates. For most positive outcomes, gatekeepers should be from a different functional area, and have the authority to commit financial and human resources to the project. A predetermined set of criteria is applicable to each gatekeeper to ensure fair outcomes.

## Product Design and Development Flow Process



*A prototype is produced and assessed before the product moves towards production.*

The seven most common sequential stages of the Product Design and Development Process are as follows:

### 1. The Idea Stage

The idea stage is also commonly known as the Initial stage. This is where your food business identifies requirements for resources such as equipment, technical specialists, capability to meet regulations, testing and analysis resources. The decision to proceed with the idea is also generally made at this stage once the relevant considerations have been assessed with positive outcomes.

### 2. The Concept Stage

The concept stage is also commonly known as the Business Case stage. This is where a detailed description of the food product is documented. Peripheral requirements such as testing and analysis procedures and targets are defined, along with an assessment of the target markets to ensure the project is commercially viable.

### 3. The Prototype Stage

The prototype stage is also commonly known as the Development stage. This is where a product sample or prototype is produced, including the defining and documentation of process stages required to achieve the intended finished product. It is also at this stage that the HACCP system and quality controls are first implemented as a method of reviewing product realisation capability. Labelling and packaging design is also started within this stage of the process, along with other risk or commercial risk assessments to ensure the viability of the project.

### 4. The Pilot Production Stage

The pilot production stage is also commonly known as the "Implementation" stage. This is where the preliminary production system is finalised, along with the finished product parameters. This stage also involves the critical task of validating production systems to ensure appropriate outcomes. Regulatory approvals are often also facilitated at this stage. Business commercial realisation details are also completed at this stage. Further information can be found within the haccp.com Process Control Management Food Standard Element.

### 5. The Market Production Stage

The Market Production Stage is also commonly known as the Actual Production stage. This is where the production of actual product begins within the established facility. Product to be supplied into the marketplace is generally re-validated to ensure the anticipated parameters have been met. Commercial viability is also often re-confirmed at this stage.

### 6. The Launch Stage

The launch stage is also commonly known as the Product Realisation stage. This is where the implemented process is fine-tuned to ensure the product specifications can be met on an ongoing basis. Cost efficiencies are also generally reviewed at this stage. Marketing plans are finalised and implemented.

## 7. The Post Launch Review

The post launch review is also commonly known as the Product Design and Development Review stage. This is where the food business reviews all aspects of the project scope and purpose outcomes. Outcomes of process and product performance against specifications are reviewed, along with non-conformance issues or identified opportunities for improvements within the Product Design and Development Process.

Questions considered within the post launch review may include:

- Has the product launch met expectations?
- What is the handover plan from product development to operations?
- Is the plant consistently producing to specification?
- What did we learn from this project?

A common application within all of these stages is to designate specific tasks, responsibilities and outcomes for:

- Product and Manufacturing Technology;
- Product Assessment and Testing;
- Market Development; and
- Business Planning.

At the completion of each stage of the Product Design and Development process, a decision needs to be made regarding whether or not to continue into the next stage of the process, or to re-work that stage based upon current status and outcomes. It is important to consider that if you are developing a product for a customer, they may wish to be involved in all or specified elements of the Product Design and Development process. The outcome of each gate decision, and the reasons for it, should be recorded.

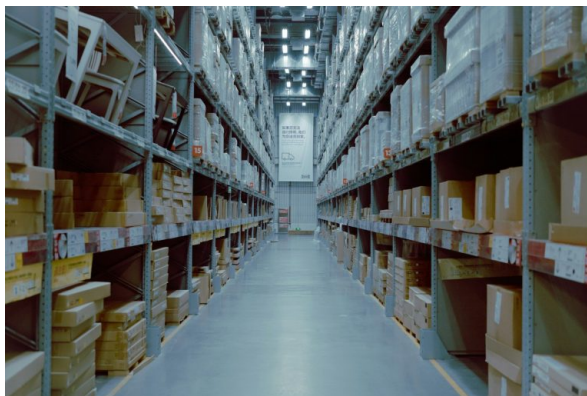
### About Contract Review

Contract review is a systemic requirement which promotes and nurtures supplier and customer relationships. For legal reasons, and for the transparency of customer expectations, contracts should be developed, documented, implemented and reviewed on an ongoing basis between suppliers and customers. Contract review processes are often closely linked to customer focus related systemic elements.

It is also important to consider that Contract Review requirements may not just be applicable to customers; they can be reversed and applied with similar methods for suppliers of materials or services. Further information can be found within the haccp.com Approved Supplier Management Food Standard Element.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific Product Design and Development requirements in relation to their items.

## Shelf Life



*Storage conditions are one of the factors that determine a product's shelf life.*

Shelf life is set during product design and development and must be supported by evidence. It is influenced by the product formulation, the process, the packaging, and the storage and distribution conditions, and it should consider microbiological, chemical, physical, and organoleptic parameters.

Shelf life considerations commonly include:

- Shelf life validation for chilled, ambient, and frozen products, using samples that are representative of the finished product and its packaging;
- Challenge testing, where the product could support the growth of pathogens or where microbiological risk requires it;
- Assessment of the risk before the shelf life of a raw material is extended, including its effect on the finished product;
- Confirmation of the storage conditions, such as temperature, that the shelf life depends on; and
- Ongoing shelf life assessment after launch, so that results are reviewed against the nominated shelf life.

Further information can be found within the haccp.com Food Microbiology Management Food Standard Element.

## References

- Codex Alimentarius codes of practice, including the General Principles of Food Hygiene;
- World Health Organization food safety fact sheet.

## Product Design and Development Key Points

- Product Design and Development programs must be developed to meet relevant Regulatory, Industry, and Customer standards and requirements;
- The Senior Management of your business facilitate a commitment to ensuring adequate resources to the development of your Product Design and Development program;
- Should you require additional resources for the development of Product Design and Development program elements, please discuss this with the relevant Senior Management representative;
- A properly developed Product Design and Development program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly-developed Product Design and Development program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

## Documentation

*To establish the developed detail in a viewable format to facilitate information.*

### Documentation

**Document:** A document provides guidance and/or direction for performing work, making decisions, or rendering judgements that affect the safety or quality of the products or services that customers receive.

Documented policies, procedures, work instructions, and schedules form the basis of any food safety and quality management system. The following documentation formats may be considered to ensure ongoing compliance with specified requirements for Product Design and Development:

- Product Design and Development policy;
- Product Design and Development development procedures;
- Product Design and Development implementation procedures and work instructions;
- Product Design and Development monitoring procedures;
- Product Design and Development corrective and preventative action procedures;
- Product Design and Development verification schedule;
- Product Design and Development verification procedures;
- Product Design and Development validation schedule;
- Product Design and Development validation procedures;
- Product Design and Development training procedures.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific Product Design and Development Documentation requirements in relation to their items.

You may wish to visit the Product Design and Development Templates section of haccp.com for examples of Product Design and Development documentation, record, and resource formats commonly applied within food safety and quality systems.

### Product Design and Development Documentation Key Points

- Product Design and Development programs must be documented to meet relevant Regulatory, Industry, and Customer standards and requirements;
- All documented Product Design and Development program elements must be controlled to ensure compliance;
- Key documented Product Design and Development program elements should be available to your business team at all times to ensure they can facilitate required tasks;
- A properly documented Product Design and Development program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly documented Product Design and Development program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

## Implementation

*To facilitate the application of the documentation.*

### Implementation

**Implementation:** Implementation is the application of documented food safety and quality system elements into the actual business operation.

The implementation of Product Design and Development within any food business requires genuine commitment from senior management, staff, and visitors to ensure the nominated goals of implementation are achievable on an ongoing basis. It is a step that requires significant planning and consideration of general and specific food business circumstances to ensure the outcomes of Product Design and Development do not negatively impact the safety and

quality of the food items dispatched from the business.

Implementation of Product Design and Development must include a clear definition of responsibilities and authorities for all levels of participation by senior management, staff, and visitors to the site.

When implementing Product Design and Development within a food safety and quality system, you may wish to consider the following requirements before completion:

- Communication and display of the Product Design and Development policy;
- Completion of Verification and Validation of Product Design and Development development procedures;
- Availability of Product Design and Development implementation procedures and work instructions;
- Availability of Product Design and Development monitoring procedures and record templates where applicable;
- Availability of Product Design and Development corrective and preventative action procedures and record templates where applicable;
- Availability of the Product Design and Development verification schedule;
- Availability of Product Design and Development verification procedures;
- Availability of the Product Design and Development validation schedule;
- Availability of Product Design and Development validation procedures;
- Completion of Product Design and Development training procedures;
- Completion of product design and development requirements related to Product Design and Development;
- Completion of process design and development requirements related to Product Design and Development;
- Completion of training for team members who have responsibilities and involvement within Product Design and Development;
- Completion of competency approval for team members who have responsibilities and involvement within Product Design and Development.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific Product Design and Development Implementation requirements in relation to their items.

### Product Design and Development Implementation Key Points

- Product Design and Development programs must be implemented to meet relevant Regulatory, Industry, and Customer standards and requirements;
- Your Product Design and Development program must be fully implemented as per relevant documented Policies, Procedures, and Work Instructions;
- The implementation of Product Design and Development requires a commitment to the provision of resources by the Senior Management of your business;
- A properly implemented Product Design and Development program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly implemented Product Design and Development program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

## Monitoring

*To review, confirm and document evidence of the implementation against documented limits.*

### Monitor

Monitoring: Monitoring is the act of reviewing and confirming measurable parameters of a defined process or product status.

Monitoring requirements within food industry sectors are generally identified against limits of acceptability defined within HACCP plans, implementation procedures, and work instructions. Monitoring usually includes some element of record-keeping, which may be maintained manually or through digital systems. Records should be controlled and retained as described within the haccp.com Document and Data Control Food Standard Element. It is important to

consider that advancements in technology have spawned many systems and processes which are self-monitored and/or self-adjusted when variances are identified. Regardless of the system used, the goal of any monitoring activity is to provide sufficient evidence that any limit of acceptability has been met.

Traditional Product Design and Development monitoring requirements include manual recording and the application of corrective actions when the results of monitoring are found to be outside acceptable limits. Corrective Actions should also generally be strongly linked to the monitoring process where applied to ensure full traceability of the applied actions.

Common monitoring activities and record formats may apply to Product Design and Development:

- Product Design and Development Project Summary: Records of the Product Design and Development Process are commonly formatted as a project summary, displaying timeframes and milestones against the nominated requirements for the relevant product and process. Where a gate process has been used, records are generally completed prior to “entering” the next defined gate phase of the project;
- Product Design and Development Log: A log of products under development, their stage, gate decisions, and responsible team members;
- Shelf Life Assessment Log: A summary of shelf life assessments and outcomes for each product;
- Shelf Life Validation Records: Evidence that chilled, ambient, and frozen finished products remain safe and meet their quality criteria for the full nominated shelf life;
- Shelf Life Challenge Testing Records: Evidence of challenge testing outcomes, where applicable;
- Raw Material Shelf Life Extension Risk Assessments: Records of the risk assessment completed before extending the shelf life of a raw material;
- Claim Validation Reviews: Records that each claim made about a product has been substantiated against regulatory and customer requirements; and
- Product Weights and Measures Validation Records: Evidence that products meet nominated weight, volume, and measure requirements.

If your food business supplies foodstuffs manufactured to a customer’s specifications, it is important to consider any specific Product Design and Development Monitoring requirements in relation to their items.

You may wish to visit the Product Design and Development Templates section of haccp.com for examples of Product Design and Development documentation, record, and resource formats commonly applied within food safety and quality systems.

### **Product Design and Development Monitoring Key Points**

- Monitoring provides real-time confirmation and evidence that your risk-based FS&Q Controls are effectively implemented;
- Product Design and Development programs must be monitored to meet relevant Regulatory, Industry, and Customer standards and requirements;
- Monitoring of Product Design and Development must be facilitated as per relevant documented Policies, Procedures, and Work Instructions;
- Nominated monitoring records for Product Design and Development must be maintained as per relevant documented Policies, Procedures, and Work Instructions;
- A properly monitored Product Design and Development program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly monitored Product Design and Development program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

## Corrective Action and Preventative Action

*To apply “real time” interventions to documented monitoring limits.*

### Corrective Action and Preventative Action

**Corrective Action:** Corrective action is mandatory action to be taken when a deviation to the Quality System occurs, particularly to a Critical Control Point.

**Preventative Action:** At any step in the process where a hazard has been identified, preventative action must be put into place to prevent re-occurrence.

Corrective Action and Preventative Action are implemented to ensure identified non-conformance issues are documented, investigated, and rectified within appropriate timeframes. Corrective action is any action applied to regain control over a product, process, policy, or procedure that has been identified as being non-conforming outside nominated limits of acceptability. Preventative action is any action applied to prevent any identified non-conformance from reoccurring.

The outcomes of corrective and preventative actions should result in regained process control after effective application. Specified corrective actions are commonly linked to the HACCP Plans and the food business certification process.

Below are Corrective Action and Preventative Action examples which may be associated with Product Design and Development related non-conformance:

- Review of the Product Design and Development policy;
- Review of Product Design and Development development procedures;
- Review of Product Design and Development implementation procedures and work instructions;
- Review of Product Design and Development monitoring procedures;
- Review of Product Design and Development corrective and preventative action procedures;
- Review of the Product Design and Development verification schedule;
- Review of Product Design and Development verification procedures;
- Review of the Product Design and Development validation schedule;
- Review of Product Design and Development validation procedures;
- Review of Product Design and Development training procedures;
- Retraining in Product Design and Development;
- Review of management review activities to include Product Design and Development as an agenda item;
- Initiation of product hold procedures where safety or quality may be compromised;
- Review of shelf life where validation or assessment shows that the nominated shelf life is not supported;
- Review or withdrawal of any claim that cannot be substantiated;
- Review of weights and measures controls where a product does not meet nominated requirements;
- Review of a gate decision, including a decision to hold or stop the project, where new information is identified;
- Initiation of a product recall or product recall procedures where investigations show that there is a substantial safety and/or quality risk to the released product;
- Contacting stakeholders including customers regarding any confirmed or potential Product Design and Development concerns involving their product.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific Product Design and Development Corrective Action requirements in relation to their items.

You may wish to visit the Corrective Action and Preventative Action section of [haccp.com](http://haccp.com) for examples of best practice applications for this food safety and quality system element.

## Product Design and Development Corrective Action and Preventative Action Key Points

- The implementation of Corrective Action and Preventative Action provides confidence that your FS&Q Program is effectively implemented and that FS&Q criteria are being met;
- Where deviations or variations are observed, Corrective Action and Preventative Actions must be facilitated to meet relevant Regulatory, Industry, and Customer standards and requirements;
- Corrective Action and Preventative Action of Product Design and Development must be facilitated as per relevant documented Policies, Procedures and Work Instructions;
- Records of Corrective Action and Preventative Action for Product Design and Development must be maintained per relevant documented Policies, Procedures and Work Instructions;
- Proper application of Corrective Action and Preventative Action for your Product Design and Development program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- Poor application of Corrective Action and Preventative Action for your Product Design and Development program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

## Verification

*To review and confirm documented monitoring and corrective actions against documented parameters.*

### Verify

Verification: The act of reviewing, inspecting, testing, checking, auditing, or otherwise establishing and documenting whether items, processes, services, or documents conform to specified requirements.

Verification is the detailed review of all food safety and quality system elements to confirm that they are effectively developed, documented, implemented, monitored, and reviewed. All food safety and quality system elements, including documented policies, procedures, training, HACCP plans, and their operational applications must be verified on an ongoing scheduled basis. The verification process commonly includes a defined schedule for which verification activities are required, how often they are conducted, who is responsible, and detailed documented procedures for each nominated verification activity.

The general goal of an established verification process is to ensure any systemic non-conformance issues are identified and rectified within an appropriate time frame. When non-conformance issues are identified through the verification process, Corrective Actions and Preventative Actions should be implemented to ensure they do not impact the effectiveness of the food safety and quality system.

The following examples of verification activities may apply to Product Design and Development:

- Review of the Product Design and Development policy;
- Review of Product Design and Development development procedures;
- Review of Product Design and Development implementation procedures and work instructions;
- Review of Product Design and Development monitoring procedures;
- Review of Product Design and Development monitoring records;
- Review of gate decision records and project summaries;
- Review of shelf life assessment results and trends;
- Review of Product Design and Development corrective and preventative action procedures;
- Review of the Product Design and Development verification schedule;
- Review of Product Design and Development verification procedures;
- Review of the Product Design and Development validation schedule;
- Review of Product Design and Development validation procedures;
- Review of Product Design and Development training procedures;
- Review of Product Design and Development performance since the last review and historically;
- Analytical testing of product or process to ensure the effectiveness of Product Design and Development;

- Inclusion of Product Design and Development as an agenda item within the Management Review Process.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific Product Design and Development Verification requirements in relation to their items.

You may wish to visit the Verification Activities section of haccp.com for examples of best practice applications for this food safety and quality system element.

### Product Design and Development Verification Key Points

- Your verification program provides evidence that your FS&Q Controls have worked;
- Product Design and Development programs must be verified to meet relevant Regulatory, Industry, and Customer standards and requirements;
- The verification of Product Design and Development must be facilitated as per relevant documented Policies, Procedures, and Work Instructions;
- Nominated verification records for Product Design and Development must be maintained as per relevant documented Policies, Procedures, and Work Instructions;
- A properly verified Product Design and Development program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly verified Product Design and Development program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

## Validation

*To confirm the documented monitoring or procedural limits.*

### Validate

Validation: The process of gathering evidence to provide a scientific basis for the documented act of demonstrating that a procedure, process, and activity will consistently lead to the expected results. It often includes the qualification of systems and equipment.

Validation is the provision of evidence to support the limits of control or acceptability for food safety or quality parameters nominated within systemic elements. Limits of control or acceptability are commonly included within documented food safety and quality systems elements such as procedures, HACCP plans, and specifications.

Common sources of validation include regulatory and legislative standards, finished product specifications and customer requirements, industry codes of practice and guidelines, verified and validated research, historical product and process control outcomes, and analytical testing.

The general goal of an established validation process is to ensure any systemic non-conformance issues are identified and rectified within an appropriate time frame. When non-conformance issues are identified through the validation process, corrective actions and preventative actions should be implemented to ensure they do not impact the effectiveness of the food safety and quality system.

Validation activities are commonly defined within the verification schedules and procedures of established food safety and quality management systems.

The following examples may apply to validation of the limits of control or acceptability for Product Design and Development:

- Confirmation of nominated food safety and food quality control limits for Product Design and Development. These limits may apply to regulatory, industry, customer, or finished product specifications;
- Confirmation of product shelf life through shelf life validation for chilled, ambient, and frozen products, and challenge testing where applicable;
- Confirmation of the risk assessment completed before extending the shelf life of a raw material;
- Confirmation that each claim made about a product is substantiated;
- Confirmation of product weights and measures; and

- Confirmation of analytical testing methods being used to confirm the effectiveness of Product Design and Development and ensure the accuracy of outcomes.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific Product Design and Development Validation requirements in relation to their items.

You may wish to visit the Validation Activities section of haccp.com for examples of best practice applications for this food safety and quality system element.

### Product Design and Development Validation Key Points

- Your validation program provides evidence that your FS&Q Controls will work;
- Product Design and Development programs must be validated to meet relevant Regulatory, Industry, and Customer standards and requirements;
- The validation of Product Design and Development must be facilitated as per relevant documented Policies, Procedures, and Work Instructions;
- Nominated validation records and supporting documentation for Product Design and Development must be maintained as per relevant documented Policies, Procedures, and Work Instructions;
- A properly validated Product Design and Development program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly validated Product Design and Development program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

## Training, Competency and Resources

*Skills, knowledge and competency requirements to facilitate development, documentation, implementation, monitoring, corrective action, verification and validation of every Food Safety and Quality System Element.*

### Skills and Knowledge

Skills and Knowledge: Skills and knowledge are attributes of human interactions commonly linked to competency within any specified job-related task.

Training and competency requirements for Product Design and Development must be ongoing, including regularly scheduled reviews to ensure the effectiveness of training and competency outcomes.

Team members who have defined responsibilities regarding Product Design and Development should have knowledge including:

- Basic Product Design and Development requirements;
- Positive outcomes of Product Design and Development;
- Negative outcomes of a lack of Product Design and Development;
- Current Product Design and Development procedures, methods, and techniques;
- General operational, corporate, and social awareness regarding Product Design and Development;
- Regulatory, industry, and customer requirements regarding Product Design and Development.

Team members who have defined responsibilities regarding Product Design and Development should have skills including:

- Competency regarding basic Product Design and Development;
- Effective application of current Product Design and Development procedures, methods, and techniques;
- The basic development, documentation, and implementation of HACCP and Prerequisite Programs within the food industry sector.

Team members who have defined responsibilities regarding Product Design and Development should have access to resources including:

- Product Design and Development training;

- Product Design and Development associations and events;
- Regulatory standards, industry and customer information and updates regarding Product Design and Development;
- Incidents within the food industry sector regarding Product Design and Development;
- Commitment to Product Design and Development by senior management;
- Suitably qualified food industry professionals with verified experience in Product Design and Development;
- Effective communication systems including email, internet, and phone through which Product Design and Development information can be sent and received within suitable timeframes.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific Product Design and Development Training, Competency, and Resources requirements in relation to their items.

You may wish to visit the Training, Competency, and Resources section of haccp.com for examples of best practice applications for this food safety and quality system element.

### Product Design and Development Training, Skills, and Knowledge Key Points

- Your Training, Skills, and Knowledge program ensures all participating personnel, visitors, and contractors have the required skills and knowledge to effectively facilitate the requirements of your FS&Q Program;
- Training, Skills and Knowledge programs for Product Design and Development must be facilitated to meet relevant Regulatory, Industry, and Customer standards and requirements;
- Training, Skills and Knowledge programs for Product Design and Development must be facilitated as per relevant documented Policies, Procedures, and Work Instructions;
- Training, Skills, and Knowledge records for Product Design and Development must be maintained as per relevant documented Policies, Procedures, and Work Instructions;
- Properly applied Training, Skills, and Knowledge programs for Product Design and Development will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- Poorly applied Training, Skills, and Knowledge programs for Product Design and Development will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.



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