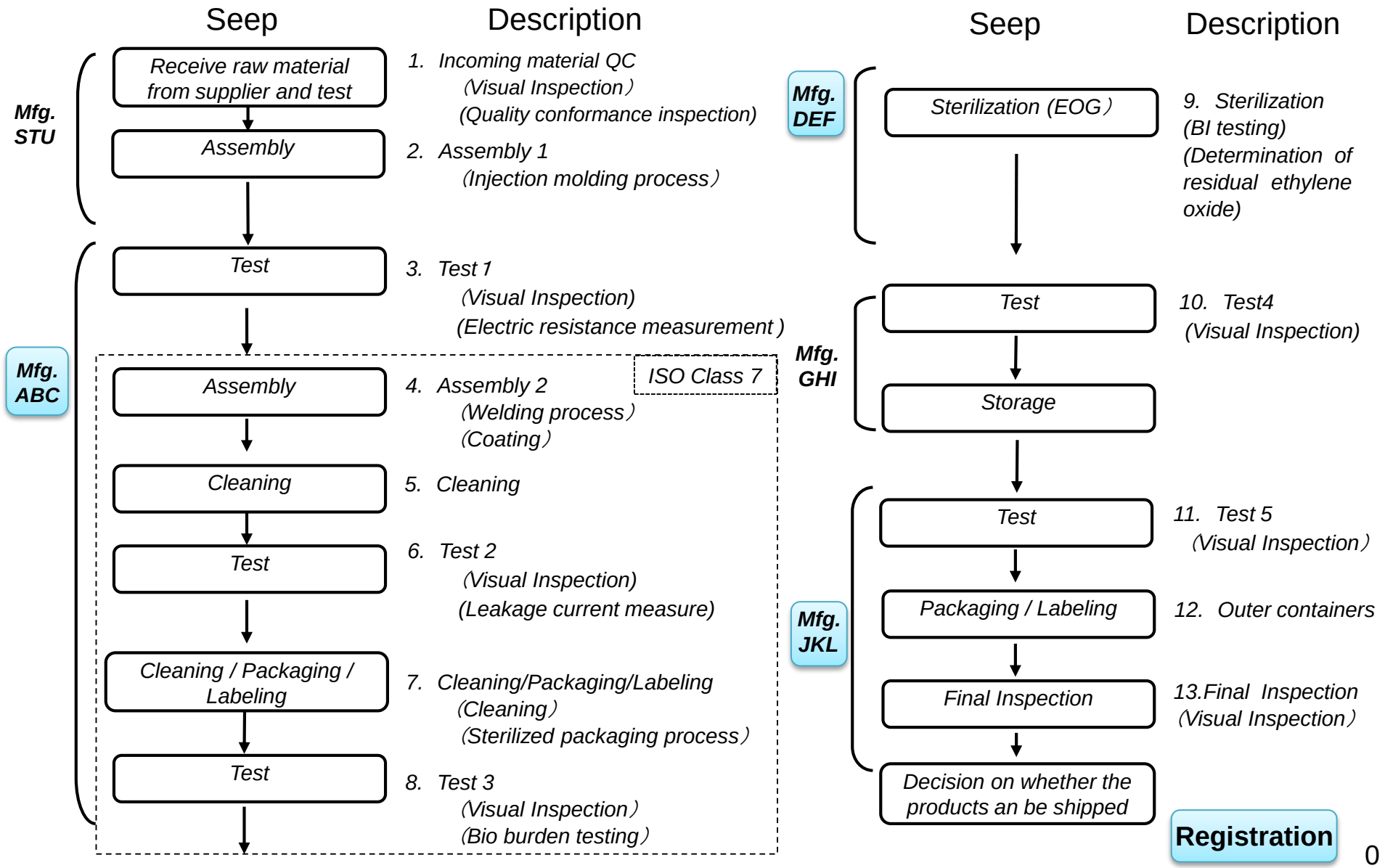
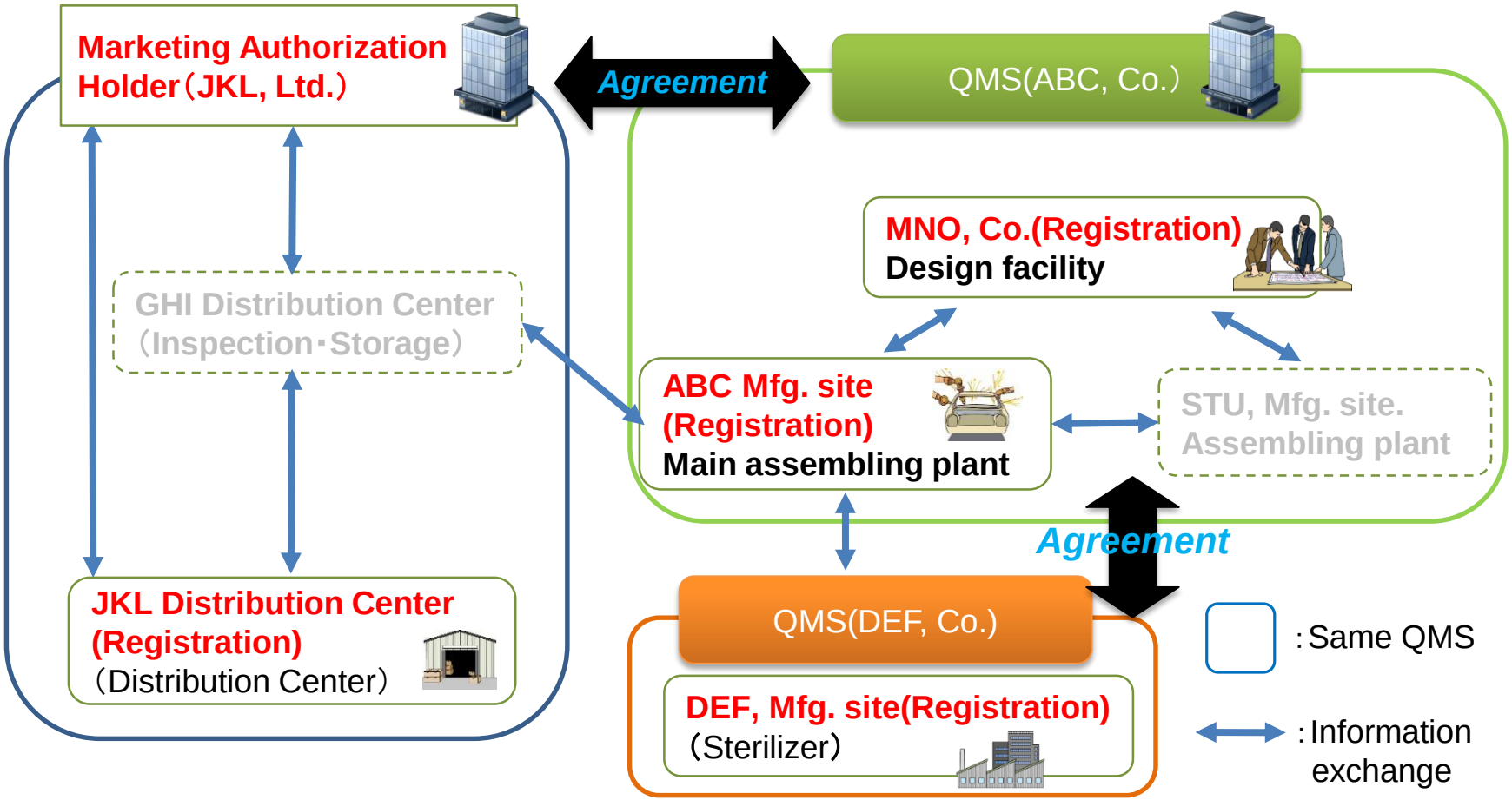
Example

# Sample1 Manufacturing process flow.



Example

# Sample2 Mutual relations of QMS



Example

# Form2 Outline of MAH/RMS (1/2)

## Outline of manufacturing site

As of DD/MM/YY

| | | | |
|---|---|---|---|
| Name of mfg . site | | | |
| Address of mfg. site | | | |
| Registration number | | Date of initial registration | |
| Registration period | | | |

Numbers of employees (including part time employees)

| | | |
|---|---|---|
| Total: | Mfg. department : | QA/QC department : |

Number of mfg. products (Number of products exported to Japan should be described in parenthesis.)

| | *Class I* | *Class II* | *Class III* | *Class IV* |
|---|---|---|---|---|
| Number of products | | | | |
| Product utilizing medicine/cellular and tissue-based product | | | | |
| Specified biological product | | | | |
| Product utilizing nano materials | | | | |
| Micro machine | | | | |
| Product absorbed into human body | | | | |
| Special designated medical device | | | | |

Example

# Form2 Outline of RMS (2/2)

If export , please describe your export destination and trade name of the products except Japan.

| Export destination | Trade name of the product |
|---|---|
| | |

| | |
|---|---|
| Changes history of mfg. site (please select items, and specify details.) | ☐ Changes of product / mfg. process (if important)<br>☐ Changes of QMS organization<br>☐ Changes of top management or management representative<br>☐ Others ( )<br>☐ No Change |
| | Details |

Not applied article 4 and article 83 of QMS ordinance (MHLW Ministerial Ordinance No.169 in 2004)

| |
|---|
| |

History of QMS inspections by regulatory authorities and registered certification body over the past 5 years.

| Name regulatory authorities/registered certification body | Inspection date | The products subject to the inspection | Inspection results | Type of Inspection (On-site or Desk-top) |
|---|---|---|---|---|
| | | | | |

Name, address, and applicable mfg. process of critical suppliers

| Name | Address | Applicable mfg. process |
|---|---|---|
| | | |

Example

# Form3 Products list for application

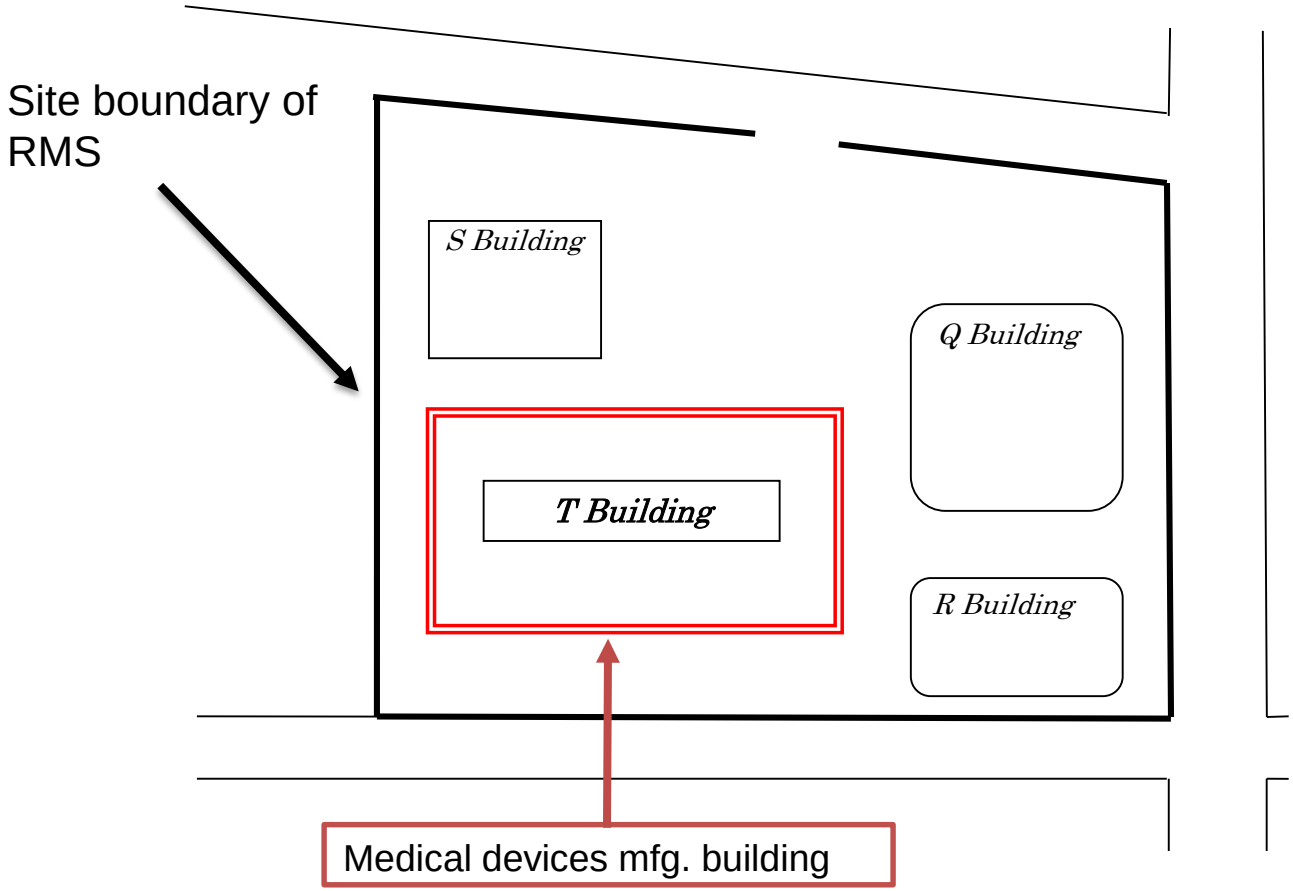
| No. | Product family | Generic name | Trade name | Approval (certification) No. | classification | Date of approval (Certification) | Expiry date | * Mfg. site registration |
|---|---|---|---|---|---|---|---|---|
| 1 | | | | | | | | |
| 2 | | | | | | | | |
| 3 | | | | | | | | |
| 4 | | | | | | | | |
| 5 | | | | | | | | |
| 6 | | | | | | | | |

* If sterilizer or distribution center are different, write these mfg. site's name.

Example

# Sample3 Layout of RMS

## Location map of RMS

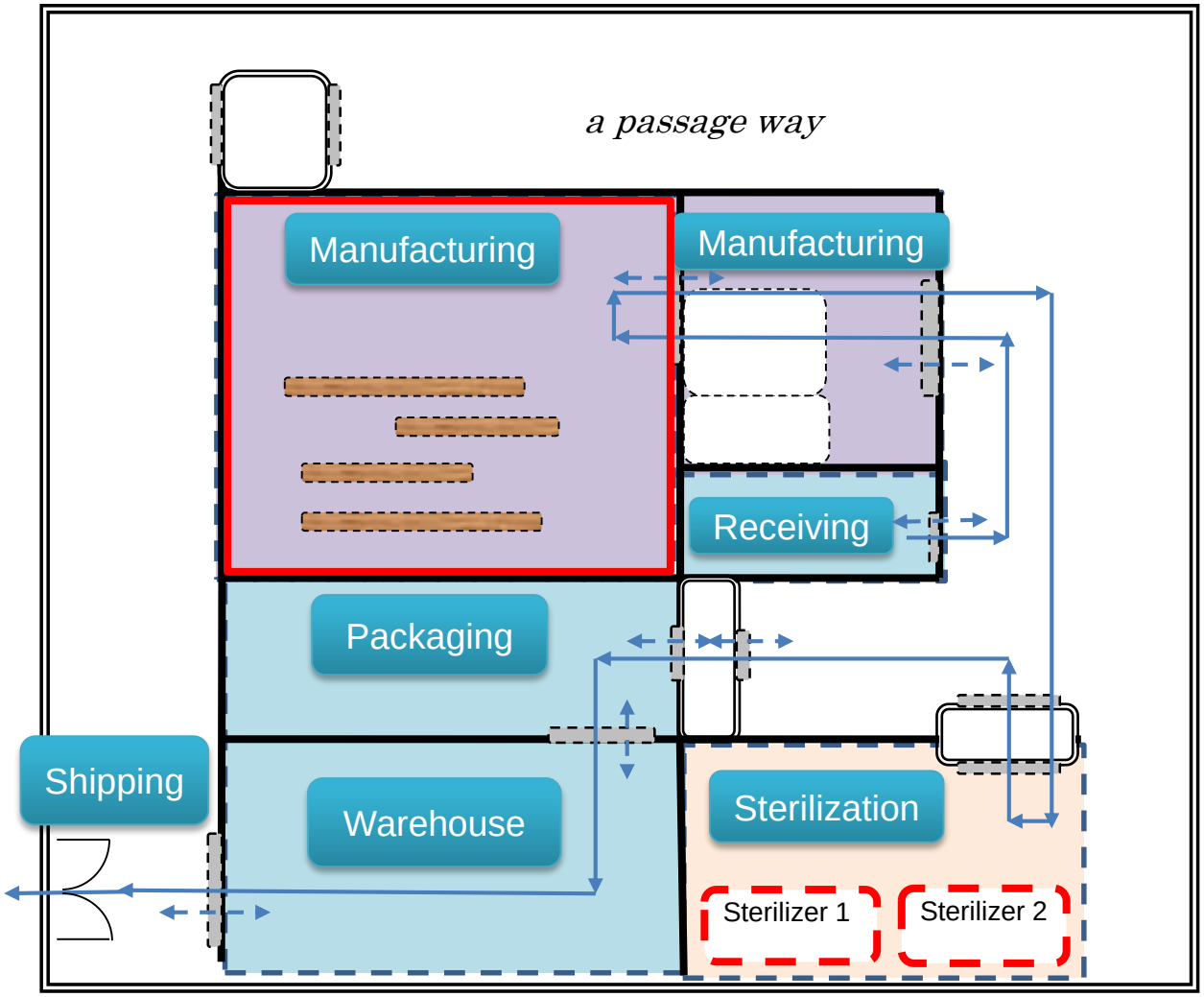



Aerial photograph or location map of RMS.

Distinguish a building affecting a subject of product.

Example

# Sample4 Floor plan of RMS(1/2)




ISO Class 7 differential pressure (>10Pa)

Sterilizer

People flow

Material flow

Example

# Sample4 Floor plan of RMS(2/2)

## Representative list of mfg. equipment

| No. | Manufacturing Equipment | Model |
|---|---|---|
| 1 | Injection Molding Equipment | SK-123 |
| 2 | Welding Equipment | Ly-222 |
| 3 | Autoclave | ST999 |
| … | … | … |

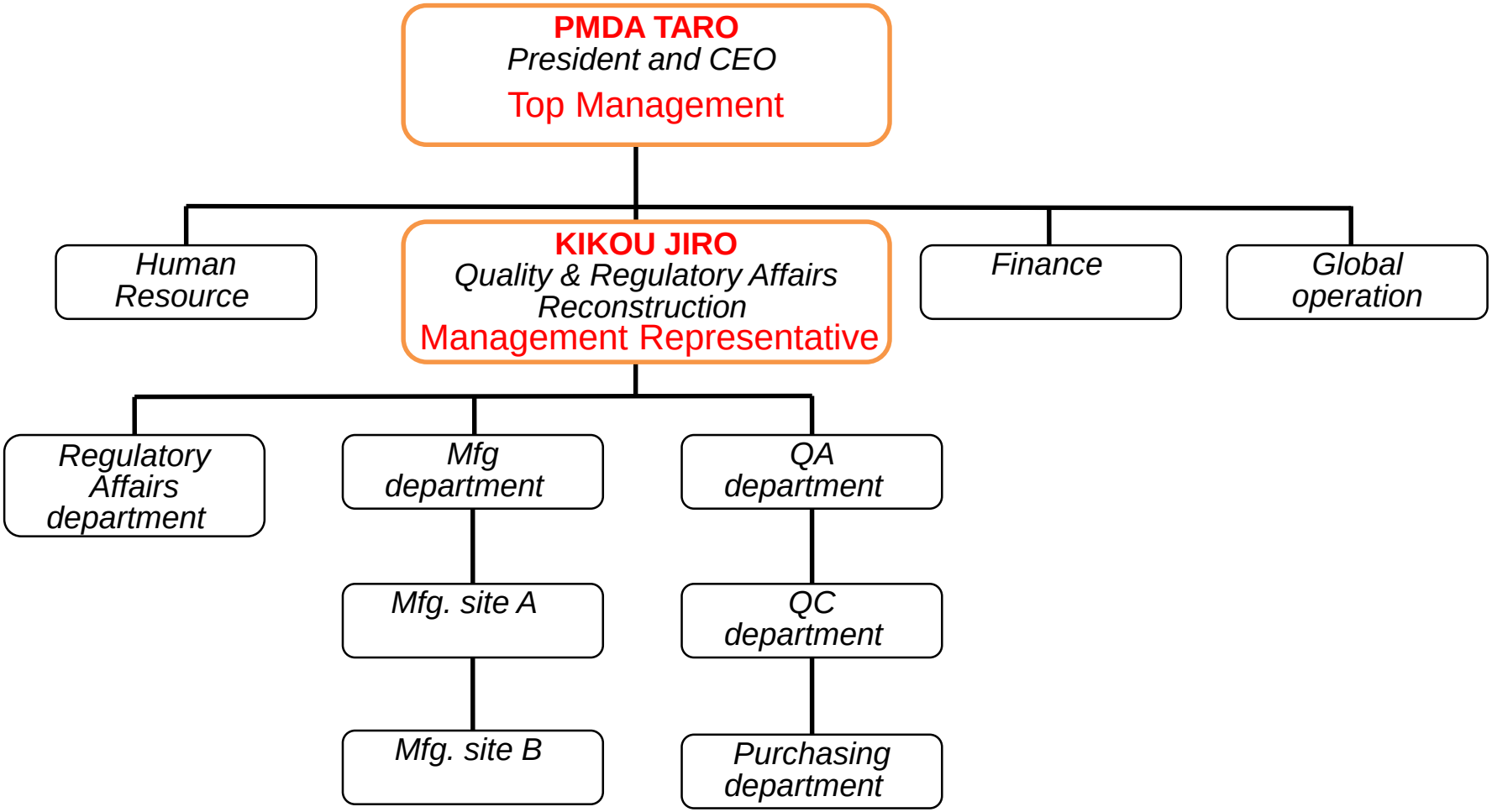
## Representative list of inspection equipment

| No. | Inspection Equipment | Model |
|---|---|---|
| 1 | Gage Blocks | 123F |
| 2 | Microscope | F111 |
| 3 | Electronic scale | SEW124 |
| … | … | … |

Example

# Sample5 organization chart

## ABC company Organization Chart



# Sample6
# List of documents identified with QMS

Example

| QMS | Article | Documents identified with the QMS | Control of documents | | Retention period |
|---|---|---|---|---|---|
| | | | Name | Number | |
| Section 2<br>QMS | | | | | |
| Article 5<br>General equirements for QMS | | | | | |
| Article 6<br>Documentation of QMS | 6.1.1 | Quality policy | | | |
| | 6.1.1 | Quality objectives | | | |
| | 6.1.2 | The quality manual | | | |
| | 6.1.5 | Any other documentation specified by the laws, others and ordinances related to the PMD Act | | | |
| | 6.2 | Seihin hyojun syo | | | |
| Article 7<br>Quality Manual | | | | | |
| Article 8<br>Control of Documents | 8.2 | Procedure about control of documents | | | |
| Article 9<br>Control of Records | 9.2 | Procedure about control of records | | | |
| .********** | *** | ********** | | | |

Example

# Sample7 Seihin Hyojyun Syo

| Requirements | Reference documents(name, number, etc) | Location (sites) |
|---|---|---|
| 1.Product family, Generic name (common name), Proprietary name | *Copy of marketing approval* | |
| 2.The date of number of approval | *Copy of marketing approval* | |
| 3.Specifications | *Product Specification*<br>*(P2/D2 DMF1 device requirement spec 73345)* | |
| 4.Operating methods and procedure | *Product Manual 7233* | |
| 5.Product design, drawings and specifications or composition and content | *Mechanical Specification 7810*<br>*(Spec-controlled environment area)*<br><br>*Test specification T78910*<br>*(Electrical test specification, IPG)*<br><br>*Product Specification P78910*<br>*(DMF1 RV2 product configuration)* | |
| 6.Mfg methods and procedure | *Mfg procedure(MT123, SOP04, SOP05)* | |
| ********** | ********** | |
| 8.Labeling and packaging | *Product Specification 1234*<br>*(P2/D2 DMF1 device requirement spec)* | |
| ********** | ********** | |

# Sample8
# Implementation of validation status

Example

| Mfg process | Validation date | | | Mfg. site | Reasons | Mfg equipment |
|---|---|---|---|---|---|---|
| | IQ | OQ | PQ | | | |
| *Injection molding* | *N/A* | *N/A* | *1/3/2014* | *ABC* | *Re-Validation* | Injection molding machine *A-01* |
| *Soldering* | *1/1/2014* | *1/2/2014* | *1/3/2014* | *ABC* | *Repairing Soldering iron D-01, D-02* | *Soldering iron D-01, D-02* |
| *Welding* | *1/1/2014* | *1/2/2014* | *1/3/2014* | *ABC* | *Change equipment* | *Ultrasonic welding machine M-01* |
| *Sterilization* | *1/1/2014* | *1/2/2014* | *1/3/2014* | *DEF* | *Purchase new sterilizer(EOG)* | *Sterilizer P-04* |
| *Packing* | *N/A* | *1/2/2014* | *1/3/2014* | *ABC* | *Change setting value (Temp:105℃→110℃)* | *Heat Sealer P-01* |
| *** | *** | *** | *** | *** | *** | *** |