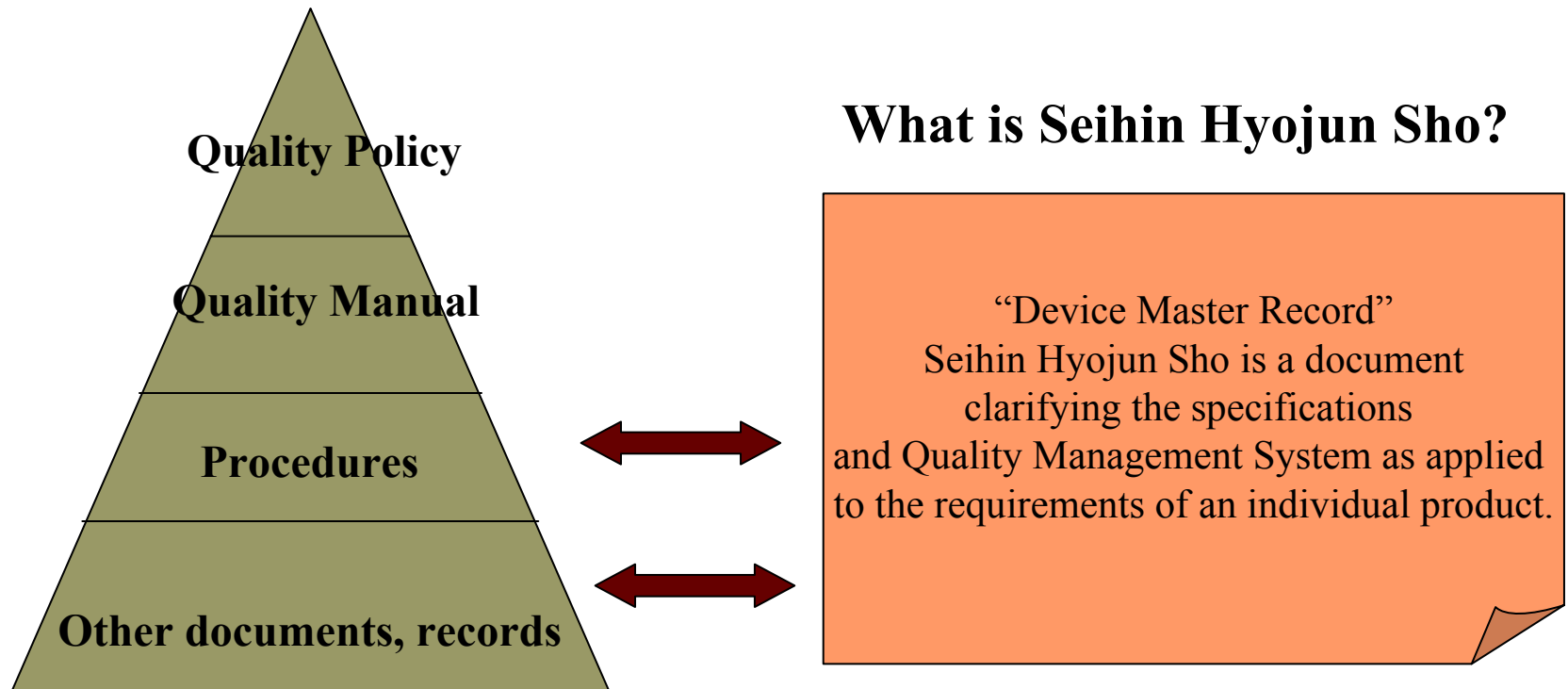


Differences Between Japanese QMS and ISO 13485

QMS	ISO13485	QMS clauses	QMS	ISO13485	QMS clauses
Article 4	—	Application	Article 35	7.3.6	Design validation
Article 5	4.1	Requirements for QMS	Article 36	7.3.7	Design change
Article 6	4.2.1	Documentation for QMS	Article 37	7.4.1	Purchasing
Article 7	4.2.2	Quality manual	-4		Evaluation of supplier
Article 8	4.2.3	Document control	-5		
Article 9	4.2.4	Record control	Article 38	7.4.2	Purchasing review
Article 10	5.1	Management	Article 39	7.4.3	Verification of purchased product
Article 11	5.2	Customer's relation	Article 40	7.5.1	Control of product and service provision
Article 12	5.3	Quality objective	Article 41	7.5.1.2.1	Cleanliness product and contamination
Article 13	5.4.1	Quality policy	Article 42	7.5.1.2.2	Installation activities
Article 14	5.4.2	QMS plan	Article 43	7.5.1.2.3	Servicing activities
Article 15	5.5.1	Responsibility and authority	Article 44	7.5.1.3	Manufacturing control of sterile MD
Article 16	5.5.2	Responsible Engineering Manager	Article 45	7.5.2	Manufacturing process validation
Article 17	5.5.3	Internal communication	Article 46	7.5.2.2	Sterilization process validation
Article 18	5.6	Management review	Article 47	7.5.3.1	Identification
Article 19	5.6.2	Review input	Article 48	7.5.3.2.1	Traceability
Article 20	5.6.3	Review output	Article 49	7.5.3.2.2	Traceability of special designated MD
Article 21	6.1	Resources	Article 50	7.5.3.3	Status identification
Article 22	6.2	Personnel	Article 51	7.5.4	Customer property
Article 23	6.2.2	Training	Article 52	7.5.5	Product preservation
Article 24	6.3	Infrastructure	Article 53	7.6	Control of monitoring and measuring
Article 25	6.4	Working environment	Article 54	8.1	Measurement, analysis and improvement
Article 26	7.1	Planning of product realization	Article 55	8.2.1	Feedback
-5		Risk management	Article 56	8.2.2	Internal audit
-6			Article 57	8.2.3	Monitoring and measuring of process
Article 27	7.2.1	Determination of product requirements	Article 58	8.2.4	Monitoring and measuring of product
Article 28	7.2.2	Review of product requirements	Article 59	8.2.4.2	Monitoring and measuring of special
Article 29	7.2.3	Customer communication	Article 60	8.3	Control of nonconforming product
Article 30	7.3.1	Design and development planning	Article 61	8.4	Data analysis
Article 31	7.3.2	Design and development input	Article 62	8.5	Improvement
Article 32	7.3.3	Design and development output	Article 63	8.5.2	Corrective action
Article 33	7.3.4	Design review	Article 64	8.5.3	Preventive action
Article 34	7.3.5	Design verification	***GMP requirement deviation from ISO 13485		

“Seihin Hyojun Sho” Requirement in Japanese QMS and Relation to ISO 13485





Contents of Seihin Hyojun Sho (Device Master Record)

1. Generic name and trade name
2. Product approval date and number
3. Product functions and specifications
4. Operational procedure or usage
5. Product design, drawing, and specifications, or ingredients and quantity
6. Manufacturing method and procedure
7. In case of imported devices, name of country of production and/or export, names of countries where product is sold, and trade names in each country
8. Label and packaging
9. Test methods of product, materials, and components
10. Storage conditions and methods for product, materials, and components