Current Situation of Utilizing MOC

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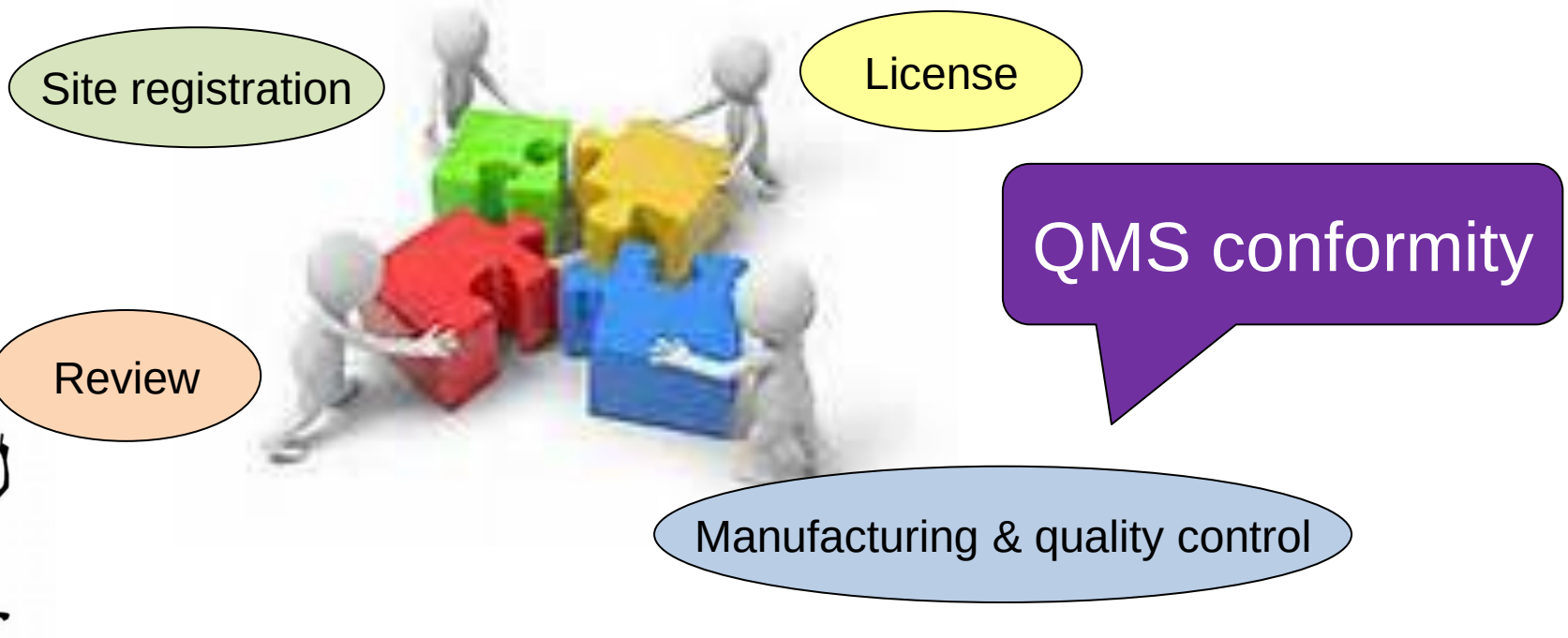
To Sell Medical Devices in the Japanese Market

Need Marketing Approval

*MAH: Marketing Authorization Holder
*D-MAH: Designated MAH

1. License of MAH/D-MAH
2. Manufacturing site registration
3. Review for application document (quality, efficacy & safety of products)
4. Conformity to QMS ordinance



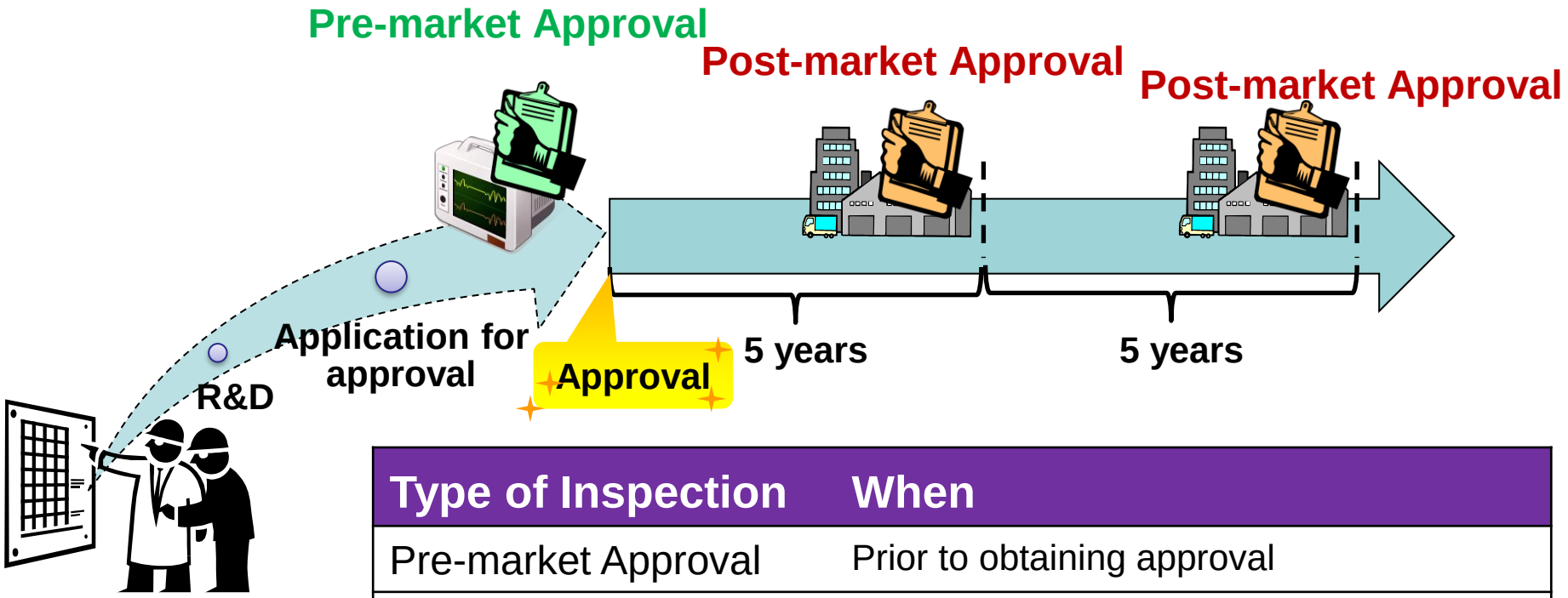
Authorities of QMS Inspection

Products		Inspection Authorities (Based on application)
Medical Devices	• Class IV • New medical devices • Cell / Tissue-based medical devices	PMDA
	• Class III and Class II (without CS*)	PMDA
	• Class III and Class II (with CS*)	Registered certification body
In-vitro diagnostics (IVDs)	• New IVDs • Radioactive IVDs	PMDA
	• Products without CS*	PMDA
	• Products with CS*	Registered certification body

*CS : Certification Standards

Type of QMS Inspection

QMS Inspection in Lifecycle of Medical Device



Type of Inspection	When
Pre-market Approval	Prior to obtaining approval
Pre-market Approval for partial change	Prior to obtaining approval of partial change (addition/ change of design sites, main assembly sites, or sterilization sites)
Post-market Approval	Every 5 years since initial approval
Additional	Required for notified cases

QMS Inspection Flow

Receive application of QMS inspection

Decide to use on-site or desktop inspection

* Example

* On-site

* Desktop

MAH

Mfg. site A (assembly)

Mfg. site B(design)

Mfg. site C (distribution)

Assess conformity to QMS ordinance

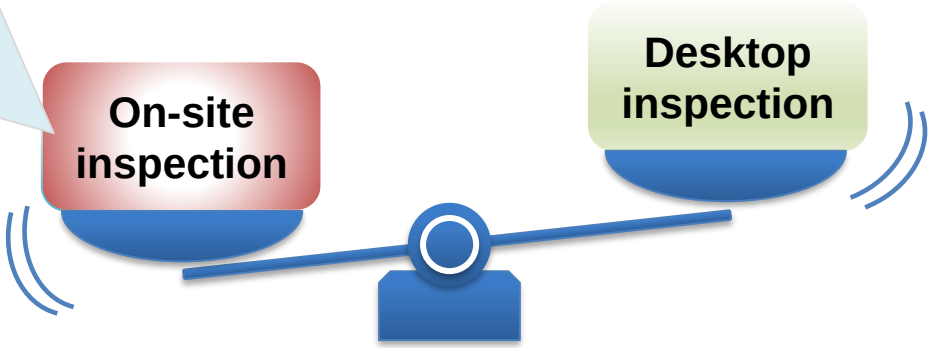
Issue compliance certification and inspection report

Decision of On-site/ Desktop Inspection

Input Information

- Submitted documents
- Reported adverse events
- Reported recalls
- Complexity of manufacturing processes
- Risks associated with the use of products
- Results and nonconformities of the previous inspections
- **Audit results by other regulatory authorities/organizations**

Risk-based Assessment



Audit Results by Other Regulatory Authorities/ Organization

PSEHB/CND Notification No.0326-12, Mar.26, 2021, appendix1

- Certificates of ISO13485 within 3 years and their latest audit reports issued by certification bodies recognized by regulatory authorities in Japan, US, Canada, EU and Australia
- On-site site audit reports within 3 years issued by the registered certification body in Japan.
- For foreign manufacturing sites in partner countries etc. with which Japan has concluded an MOU etc., when a copy of a certificate of suitability or a QMS inspection report issued by the partner country etc. based on prescriptions of the MOU etc. has been submitted, or other certain requirements have been satisfied.

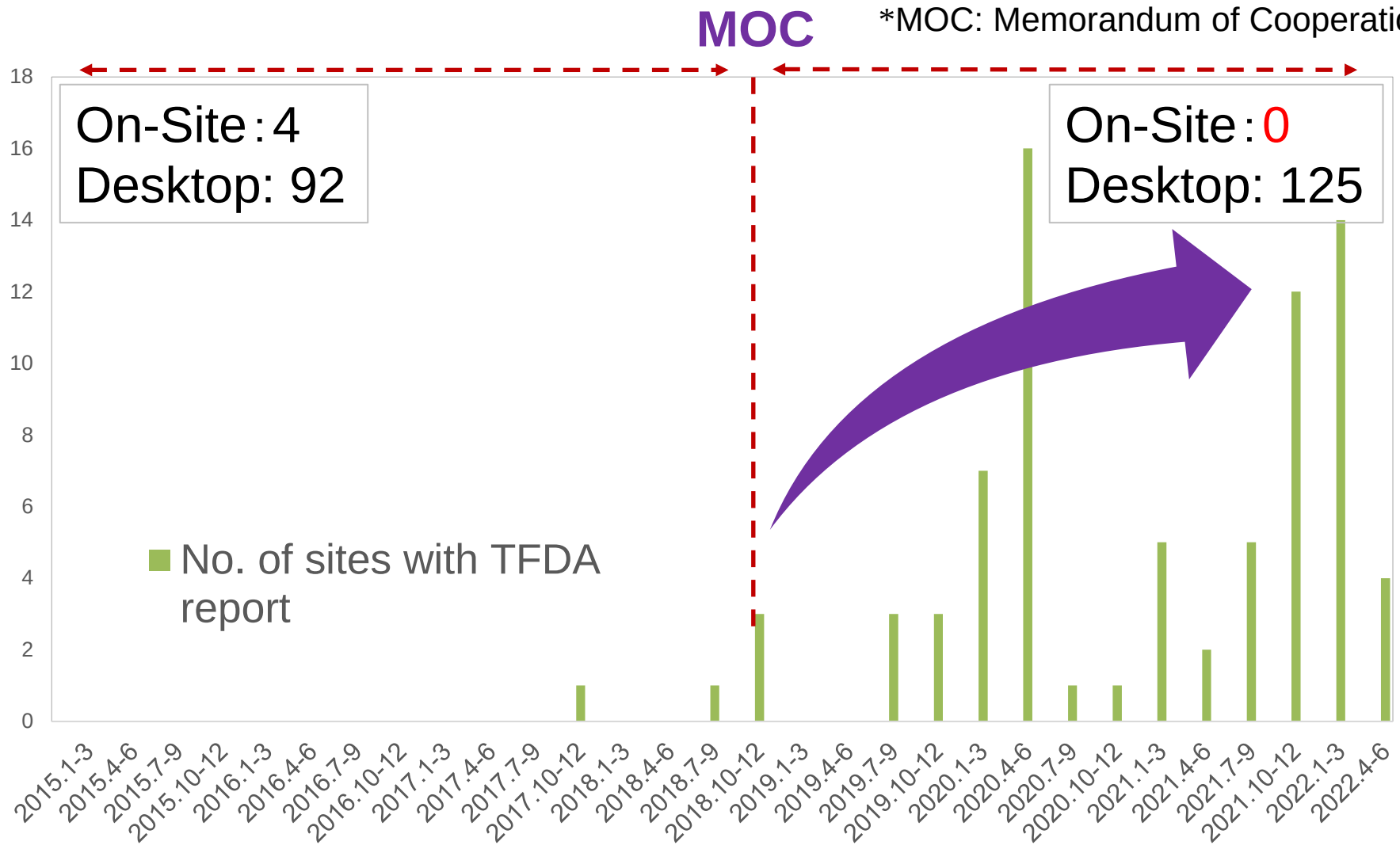
etc.

Other valid information

- MDSAP reports in initial or recertification inspection.

*MOU: Memorandum of Understanding
*MDSAP: Medical Device Single Audit Program

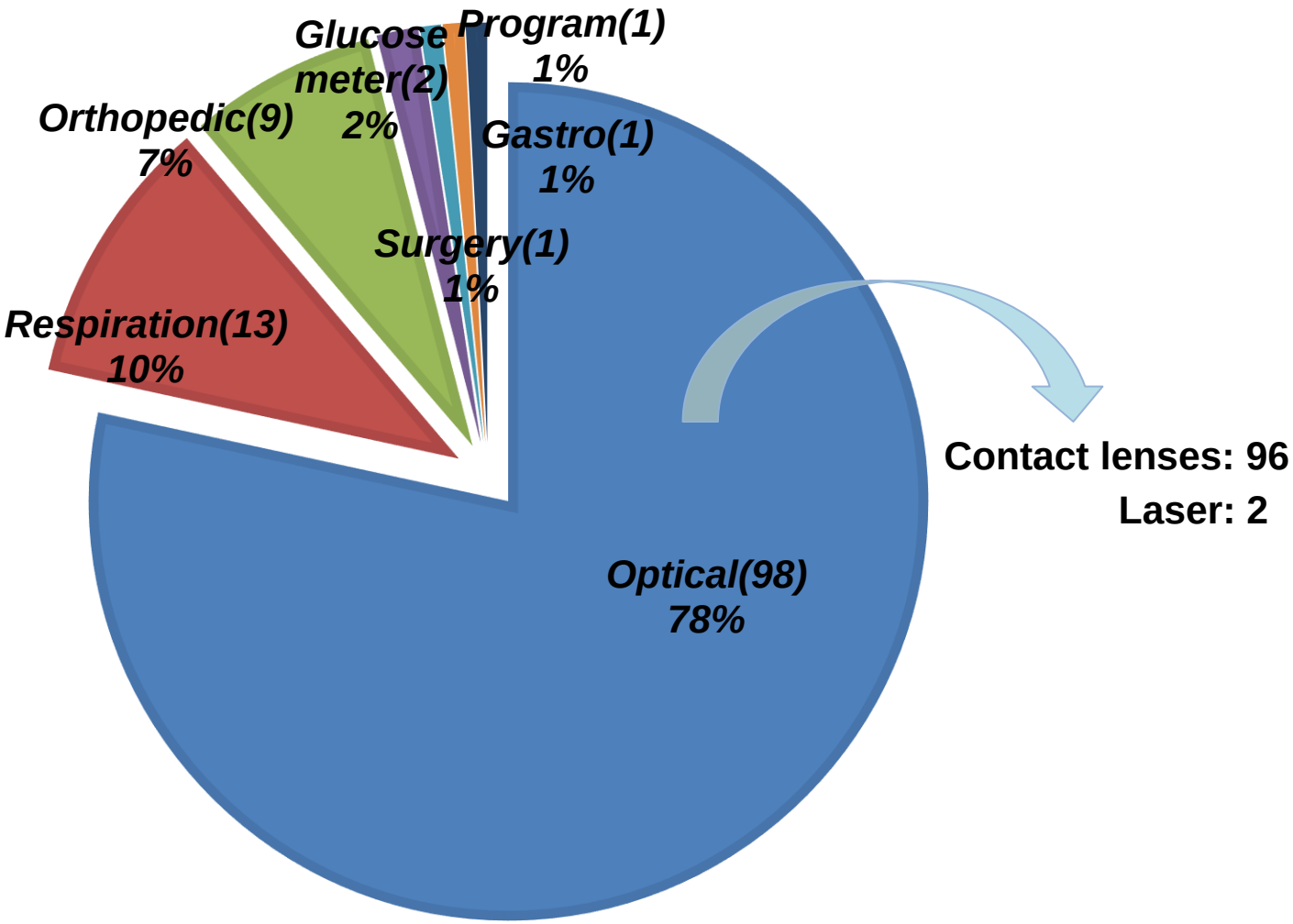
No. of Sites with TFDA Report & No. of On-site/ Desktop Inspections



The number of sites utilizing MOC is increasing.

Breakdown of Inspected Products

On-Site : 0
Desktop: 125



Optical products occupy the largest area of inspected products.

Message to Taiwanese Manufacturers

If you have the TFDA audit report already, please proactively submit it to Japanese MAH/D-MAH.

<Background>

- Taiwanese manufacturers are having more TFDA audit reports recently, but those audit reports are not submitted to the QMS application of Japan in many cases.
- The on-site QMS could be skipped if the TFDA audit reports are submitted to PMDA.
- Therefore, if Taiwanese manufacturers are included in the QMS application, PMDA asks Japanese MAH/D-MAH whether they have the TFDA audit reports.

Future Prospects

- We will keep up efforts to foster our reliable mutual relationships with regulators and manufacturers in Taiwan.
- Hopefully, both Taiwanese and Japanese manufacturers will proactively utilize the schemes under QMS MOC more.
- Both Taiwanese and Japanese patients can receive benefits from safer, more effective and innovative medical devices as soon as possible by close collaborative efforts between regulators.

Any questions?