국제공통허가심사서류
(Regulated Product Submission)

2022.9.2

식품의약품안전처
식품의약품안전평가원

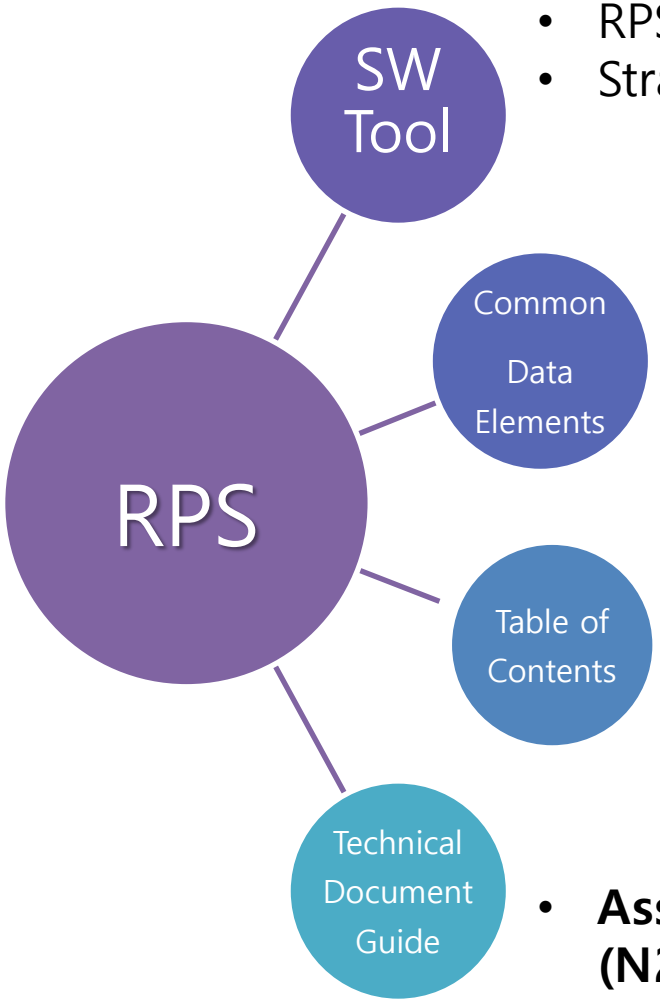
목 차

1. RPS 소개

RPS 소개 – 추진 배경

- ✓ RPS is a Health Level 7 (HL7) standard that supports **electronic submission of information for regulated products**
  - 의료기기 국제표준화기술문서(STED)를 대체하여 국제공통으로 적용할 수 있는 허가 심사서류 시스템 및 양식
  - Provides context for how the submission should be routed and reviewed (i.e. this is a supplement to a previous submission)
  - Allows a lifecycle of submission content (i.e. Document A replaces Document B)

RPS 소개 – 가이드라인의 구조



- RPS Beta Testing Document(2014)
- Strategic Assessment of Electronic Submission Messaging Formats(2015)

- **Common Data Elements for Medical Device Identification (N19, 2016)**
- Data Exchange Guidelines - Common Data Elements for Medical Device Identification(2017)

- **Non-In Vitro Diagnostic Device Market Authorization Table of Contents (N9, 2019)**
- **In Vitro Diagnostic Device Market Authorization Table of Contents(N13, 2019)**

- **Assembly and Technical Guide for IMDRF Table of Contents Submissions (N27, 2019)**

RPS 가이드라인

- ✓ **Common Data Elements for Medical Device Identification (N19)**
  - 의료기기 식별을 위한 공통데이터요소
- ✓ **Non-In Vitro Diagnostic Device Market Authorization Table of Contents (N9)**
  - 일반의료기기 허가심사시 제출 서류 목록
- ✓ **In Vitro Diagnostic Device Market Authorization Table of Contents (N13)**
  - 체외진단의료기기 허가심사시 제출 서류 목록
- ✓ **Assembly and Technical Guide for IMDRF Table of Contents Submissions(N27)**
  - 국제공통허가심사 제출서류 작성방법에 대한 가이드라인

RPS 가이드라인

✓ Common Data Elements for Medical Device Identification (N19)

- 모델, 재사용가능여부, 멸균 등 의료기기 식별을 위한 공통데이터요소를 그룹화
- 의료기기 식별(카탈로그, UDI)등을 설명

Data Elements/Grouping	Purpose

Medical Device Primary Identity Information
• Medical Device Name (Brand/Trade/Proprietary or Common name)
• Model
• Catalog/Reference (REF)
• Catalog/Reference (REF) Description
• Version (Software or Firmware)
• Unique Device Identifier (UDI)
  ○ Device Identifier (DI)
  ○ Production Identifier (PI)
  ▪ Serial Number
  ▪ Lot or Batch Number
  ▪ Manufacturing Date
  ▪ Expiration Date
	The value of the data elements are assigned by the Regulated Entity for the purposes of identifying and tracking the medical device throughout its life cycle.

Regulated Entity • Name • Address • Identifier • Type	These data elements as specified by the Regulatory Authority and the values provided by the Regulated Entity are for the purposes of identifying the legal party involved in a regulatory activity.
Kit Medical Device System	These data elements provide an indicator used to differentiate the grouping of different medical devices and/or accessories for the purpose of placing it on the market.
Contains Biological Materials	This data element provides an indicator for the existence of specific biologic materials in the medical device for safety purposes.
Medical Device Usage • Single Use Device • Reusable - Single Patient Use Device • Reusable - Multi-Patient Use Device	The values of the data elements are determined by the Regulated Entity for the purposes of managing risks associated with multiple use of the medical device.
Sterilization Information • Supplied Sterile • Needs Sterilization before use • Method of Sterilization	The values of the data elements are determined by the Regulated Entity for the purposes of managing risks associated with sterilization.
Regulatory Information • Medical Device Type • Medical Device Risk Classification • Submission Number • Regulatory Authorization or Marketing Number • Regulatory Authorization or Marketing Status	The values of the data elements are assigned by the Regulatory Authority for the purposes of identifying and tracking regulatory activities for a medical device through its life cycle.

RPS 가이드라인

- ✓ **Non-In Vitro Diagnostic Device Market Authorization Table of Contents (N9)**
  - 일반의료기기 허가심사시 제출해야하는 양식(포맷) 설명
  - 공통요소(Common Content) 및 국가별 제출(Regional Content)내용 포함

IMDRF/RPS WG/N9(Edition 3) FINAL:2019

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

International Medical Device Regulators Forum

Title: Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC)

Authoring Group: Regulated Product Submissions Table of Contents Working Group

Date: 21 March 2019

Elena M. Astapenko, IMDRF Chair

This document was produced by the International Medical Device Regulators Forum. There are no restrictions on the reproduction or use of this document; however, incorporation of this document, in part or in whole, into another document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the International Medical Device Regulators Forum.

RPS 가이드라인

- ✓ **Assembly and Technical Guide for IMDRF Table of Contents Submissions(N27)**
  - IMDRF ToC 제출을 위한 구성 및 기술 가이드
    - 폴더구조, 파일형식 및 이름지정 등에 대한 기술적 지침

IMDRF/RPS WG/N27 FINAL:2019

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

Title: Assembly and Technical Guide for IMDRF Table of Contents Submissions

Authoring Group: Regulated Product Submissions Table of Contents WG

Date: 24 January 2019

Elena M. Astapenko, IMDRF Chair

2. RPS ToC

IMDRF-ToC

- Total 6 chapter
  - Chapter1. Regional Administrative
  - Chapter2. Submission Context
  - Chapter3. Non-Clinical Evidence
  - Chapter4. Clinical Evidence
  - Chapter5. Labelling and Promotional Material
  - Chapter6A. QMS Procedures
  - Chapter6B. QMS Device Specific Information

IMDRF-ToC

CHAPTER 1 – REGIONAL ADMINISTRATIVE	
CH1.01	Cover Letter
CH1.02	Submission Table of Contents
CH1.03	List of Terms/Acronyms
CH1.04	Application Form/Administrative Information
CH1.05	Listing of Device(s)
CH1.06	Quality Management System, Full Quality System or Other Regulatory Certificates
CH1.07	Free Sale Certificate/ Certificate of Marketing authorization
CH1.08	User Fees
CH1.09	Pre-Submission Correspondence and Previous Regulator Interactions
CH1.10	Acceptance for Review Checklist
CH1.11	Statements/Certifications/Declarations of Conformity
CH1.11.1	Performance and Voluntary Standard
CH1.11.2	Environmental Assessment
CH1.11.3	Clinical Trial Certifications
CH1.11.4	Indications for Use Statement with Rx and/or OTC designation Enclosure
CH1.11.5	Truthful and Accurate Statement
CH1.11.6	USFDA Class III Summary and Certification
CH1.11.7	Declaration of Conformity
CH1.12	Letters of Reference for Master Files
CH1.13	Letter of Authorization
CH1.14	Other Regional Administrative Information

IMDRF-ToC

CHAPTER 2 – SUBMISSION CONTEXT	
CH2.1	Chapter Table of Contents
CH2.2	General Summary of Submission
CH2.3	Summary and Certifications for Premarket Submissions
CH2.4	Device Description
CH2.4.1	Comprehensive Device Description and Principle of Operation
CH2.4.2	Description of Device Packaging
CH2.4.3	History of Development
CH2.4.4	Reference and Comparison to Similar and/or Previous Generations of the Device
CH2.4.5	Substantial Equivalence Discussion
CH2.5	Indications for Use and/or Intended Use and Contraindications
CH2.5.1	Intended Use; Intended Purpose; Intended User; Indications for Use
CH2.5.2	Intended Environment/Setting for use
CH2.5.3	Pediatric Use
CH2.5.4	Contraindications For Use
CH2.6	Global Market History
CH2.6.1	Global Market History
CH2.6.2	Global Incident Reports and Recalls
CH2.6.3	Sales, Incident and Recall Rates
CH2.6.4	Evaluation/Inspection Reports
CH2.7	Other Submission Context Information

IMDRF-ToC

CHAPTER 3 – NON-CLINICAL EVIDENCE	
CH3.1	Chapter Table of Contents
CH3.2	Risk Management
CH3.3	Essential Principles (EP) Checklist
CH3.4	Standards
CH3.4.1	List of Standards
CH3.4.2	Declaration and/or Certification of Conformity
CH3.5	Non-clinical Studies
CH3.5.01	Physical and Mechanical Characterization
CH3.5.01.1	[Study description, study identifier, date of initiation]
CH3.5.01.1.1	Summary
CH3.5.01.1.2	Full Report
CH3.5.01.1.3	Statistical Data
CH3.5.02	Chemical/Material Characterization
CH3.5.02.1	[Study description, study identifier, date of initiation]
CH3.5.02.1.1	Summary
CH3.5.02.1.2	Full Report
CH3.5.02.1.3	Statistical Data
CH3.5.03	Electrical Systems: Safety, Mechanical and Environmental Protection, and Electromagnetic Compatibility
CH3.5.03.1	[Study description, study identifier, date of initiation]
CH3.5.03.1.1	Summary

IMDRF-ToC

CHAPTER 1 – REGIONAL ADMINISTRATIVE

Common Content

Regional Content

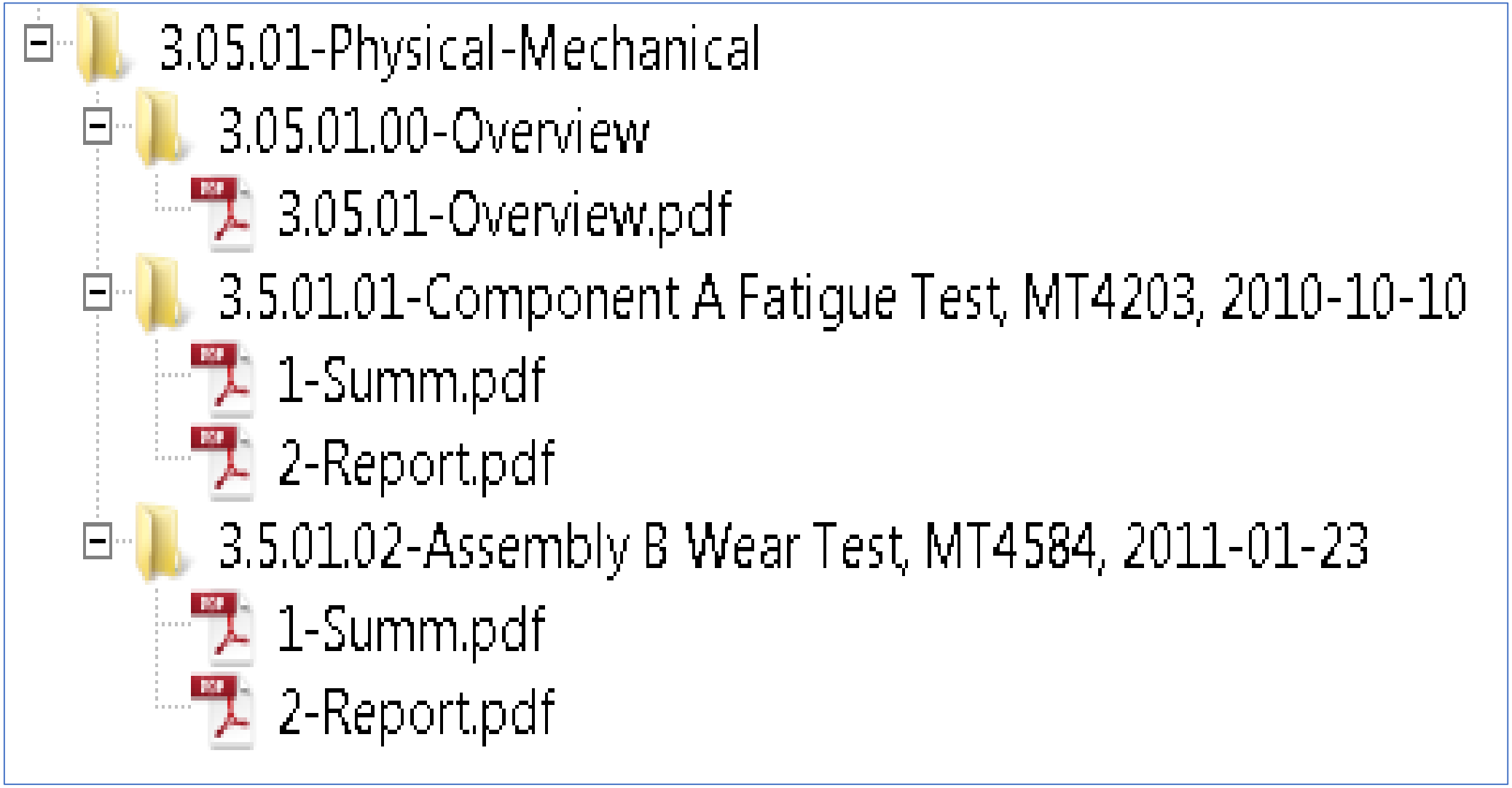
Row ID	Heading Class & Level		Heading	Common Content	Regional Content
CH1.01	IMDRF, RF	1	Cover Letter	a) The cover letter should state applicant or sponsor name and/or their authorized representative, the type of submission, the common name of the device (if applicable), device trade name or proprietary name (both of the base device and a new name if one is given to the new version/model of the device) and include the purpose of the application, including any changes being made to existing approvals. b) If applicable and accepted by the regulator, it should include information pertaining to any Master Files referenced by the submission. c) If applicable, acknowledgement that a device sample has been submitted or offered alternatives to allow the regulator to view or access the device (when the regulator requests a sample). d) If the submission is requesting approval of a change that is the result of CAPA due to a recall, this should be stated. e) If the submission is in response to a request for information from the regulator this should be stated and the date of that letter should be included as well as any reference number(s). f) If the submission is unsolicited information (where accepted), this should be stated and any related reference number(s) provided. **NOTE:** The cover letter should not contain any detailed scientific information.	**CFDA** Attached documents should be signed or sealed by applicants or by authorized representative. **USFDA PMA and 510(k)** a) mailing address, b) official correspondent(s), c) phone/fax number(s), d) email address(s e) cover letter shall be signed by applicant and an authorized rep (if the applicant does not reside or have a place of business in US) – 21 CFR 814.20(a) **(PMA Only)** f) Device class and panel or classification regulation or statement that the device has not been classified with rationale for that conclusion **(510(k) only)** **TGA** The covering letter of application needs to be prepared on company letterhead and to also include; a) Submission ID that is generated electronically when completing the application form in eBusiness b) Contact details of the person authorised to liaise with TGA during the evaluation process c) Signed by the authorised person for the company
CH1.02	IMDRF	1	Submission Table of Contents	a) Includes at least level 1 & 2 headings for the entire submission b) Specifies the page number for each item referred to in the table. **NOTE:** Refer to the Pagination Section of this document for information about submission pagination.	
CH1.03	IMDRF	1	List of Terms/Acronyms	Terms or acronyms used in the submission that require definition, should be defined here.	
CH1.04	Regional	1	Application Form/Administrative Information		**ANVISA** ANVISA´s "Manufacturer or Importer Form" (form available at www.anvisa.gov.br), containing general information related to the application. **CFDA** Application form required by Chinese Regulations (www.sda.gov.cn) **EU** Notified Bodies (NBs) will each have their own application form and company information form, including details on the submission type (new, renew, changes), administrative data of the manufacturer, overview of subcontractors and their QMS certification documentation, underlying CE certificates in case of Own Brand labelling, general information of the product, including sterilisation method where applicable, nature of selected starting materials (e.g. drugs, animal tissue), applicable directive and classification. Consult relevant NB. N.B. Under EU legislation, the Own Brand Labeller is to be considered as the legal manufacturer and bears the regulatory responsibility of a manufacturer including the need to dispose of the entire technical documentation (see the EU Guideline on OBL: http://ec.europa.eu/health/medical-

IMDRF-ToC

CH2.4	IMDRF	1	Device Description	**NO CONTENT AT THIS LEVEL**
CH2.4.1	IMDRF, RF	2	Comprehensive Device Description and Principle of Operation	a) A general description of the device, including: i. A statement of the device name ii. What the device does? iii. Who uses it and for what? (high level statement) iv. Where to use it? (places/environment where the device is intended to be used) v. How it works? Including theory surrounding feature/variants/operating modes that enable the device to be used for indications/intended use (principle of operation/mechanism of action). vi. If applicable, labelled pictorial representation (diagrams, photos, drawings). vii. If system, how the components relate?

Description

IMDRF-ToC


3.05.01-Physical-Mechanical
3.05.01.00-Overview
3.05.01-Overview.pdf
3.5.01.01-Component A Fatigue Test, MT4203, 2010-10-10
1-Summ.pdf
2-Report.pdf
3.5.01.02-Assembly B Wear Test, MT4584, 2011-01-23
1-Summ.pdf
2-Report.pdf

3. RPS WG 현황

IMDRF RPS WG 현황

✓ N9 문서 개정 작업중

- 전반적인 고려사항
  - Common Content, Regional Content 구분
- 용어, 약어 사용에 대한 논의
- Ch6 품질관리 시스템 파트 병합 논의 등
  - 6A품질관리 시스템 절차/6B품질관리 시스템 기기별 정보 파트