『개인맞춤형 의료기기(PMD) 실무그룹 업무 진행 현황 』

2022.9.2

식품의약품안전처
식품의약품안전평가원

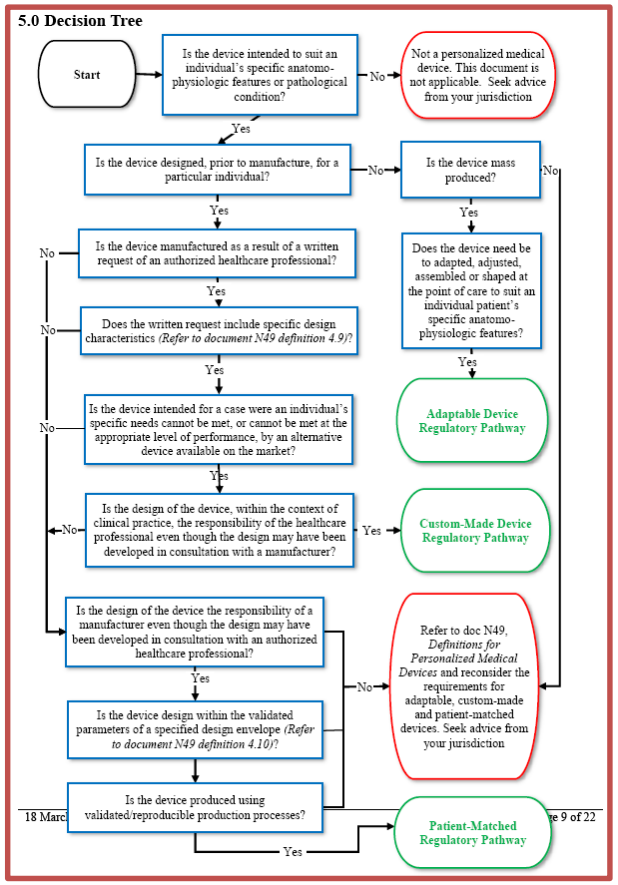
식품의약품안전처

목 차

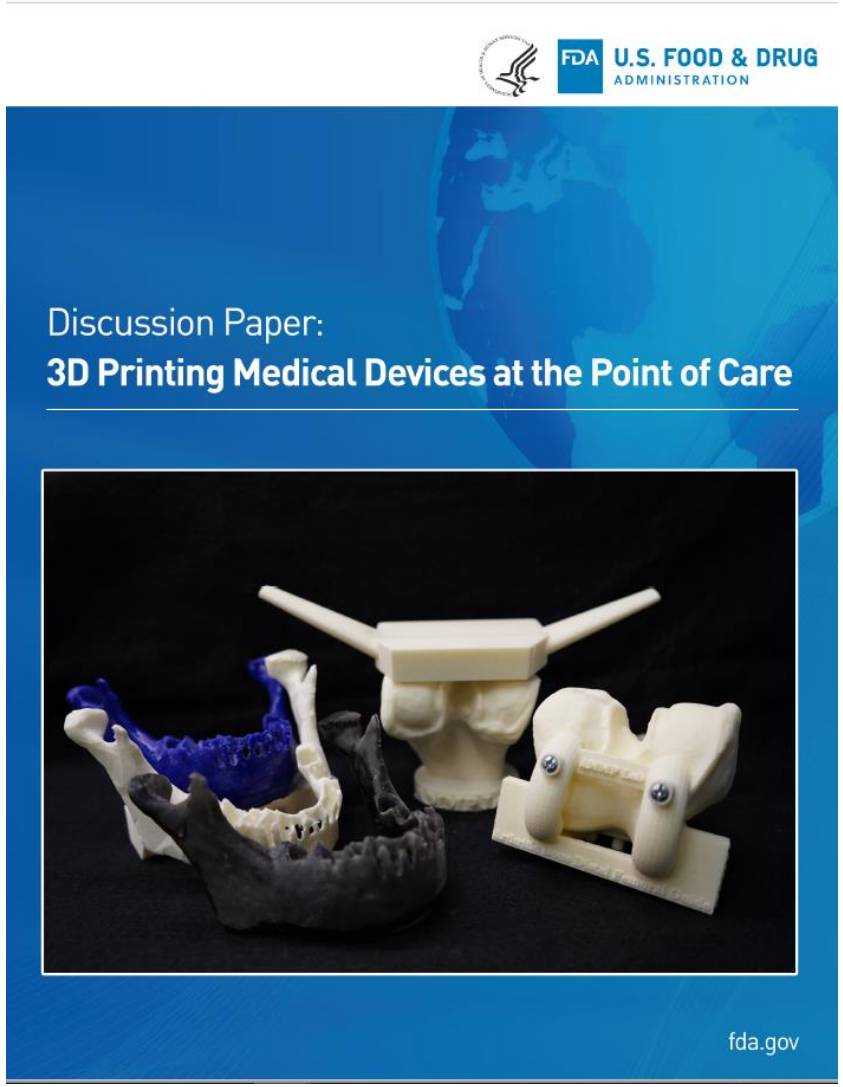
배경 및 현황

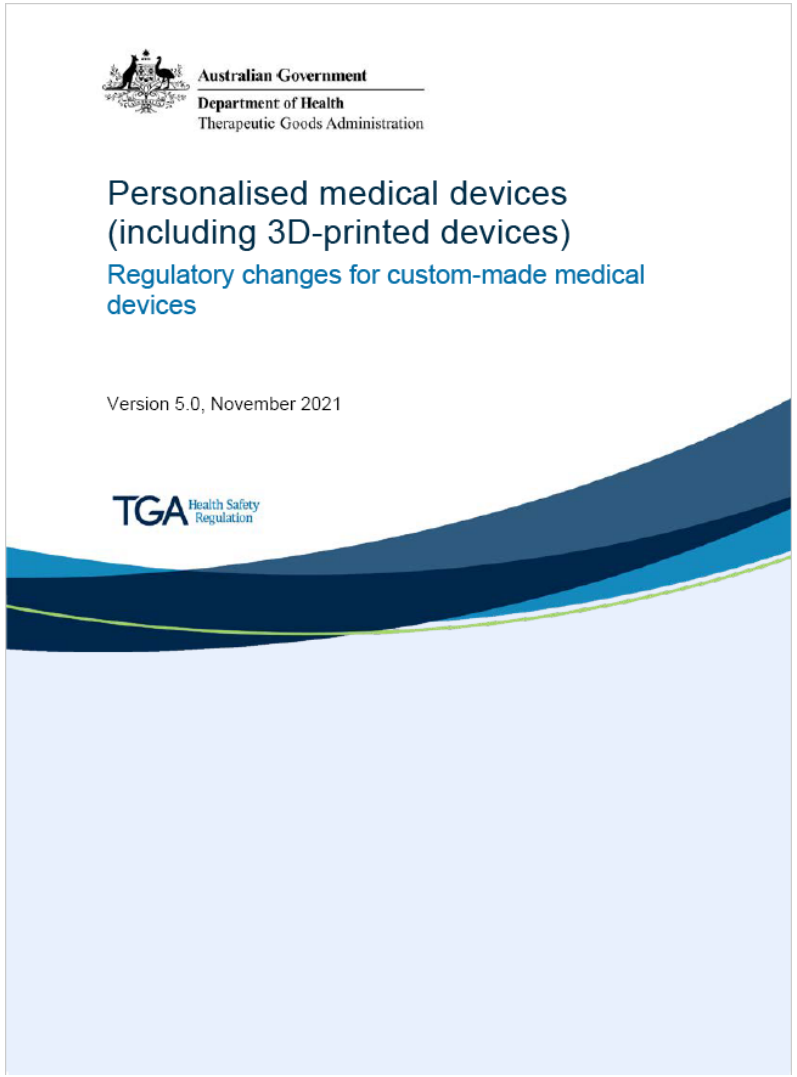
✓ 2020년 환자 맞춤형 의료기기 규제 경로 가이드라인 제정(20.3.18)

* Personalized Medical Device- Regulatory Pathways(N58)



배경 및 현황- 참고 가이드라인





PMD- Production Verification and Validation

✓ 신규 가이드라인 제정 작업 진행 중(21년 ~ 진행중)

* Personalized Medical Device – Production Verification and Validation

- Technical guidance on validation aspects of specified design envelope and medical device production system

* 가이드라인 목적(Purpose)

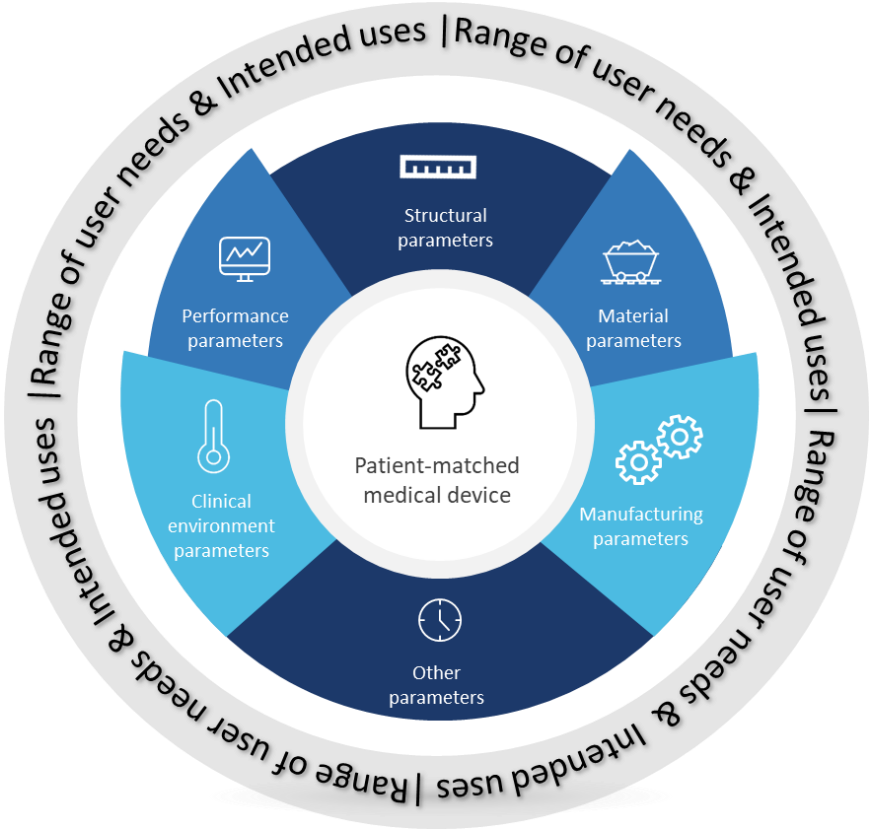
- To provide harmonized **recommendations for verification and validation aspects** of patient mated medical devices **and medical device production system(MDPS)**

* 가이드라인 범위(Scope)

- Patient-matched medical device
- Medical Device Production System
- not apply to IVD
- not apply to medical device – incorporating materials of biological origin/medicinal product/drug/active deivce, etc.

PMD- Production Verification and Validation

✓ Specified Design Envelope for patient matched medical device

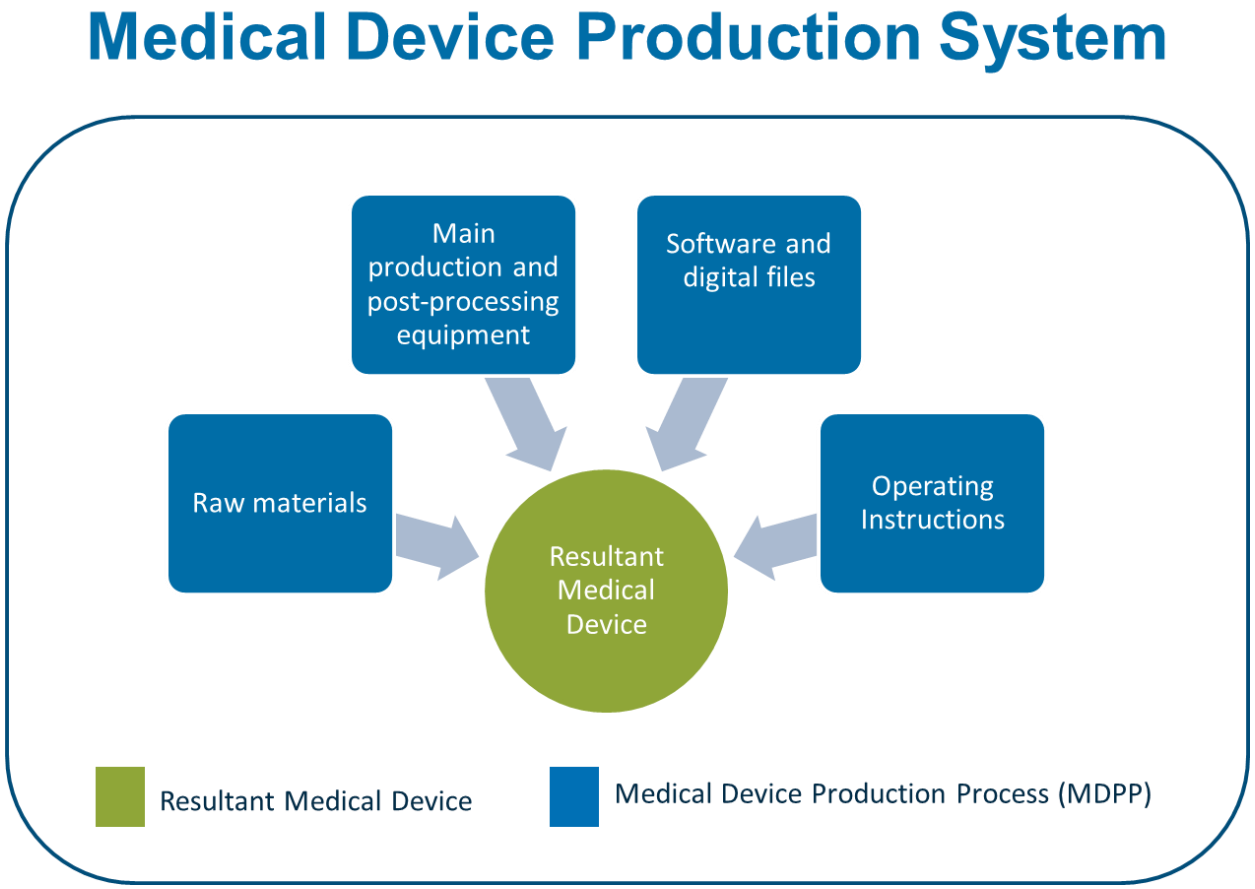


- ✓ Structural parameter
- ✓ Material parameter
- ✓ Manufacturing parameter
- ✓ Clinical environment parameter
- ✓ Performance parameter
- ✓ Miscellaneous parameter

- ✓ Validation 외 추가 고려사항
  - → Use of imaging data for patient matching
  - → Clnical evaluation
  - → labelling

PMD- Production Verification and Validation

✓ **Validation aspects of medical device production system**



PMD- Production Verification and Validation

✓ **Medical device production system = MDPP + RMD**

*** MDPP – Medical device production process**

- raw materials/ main production/ post processing equipment/ software/ digital files/ operating insturctions

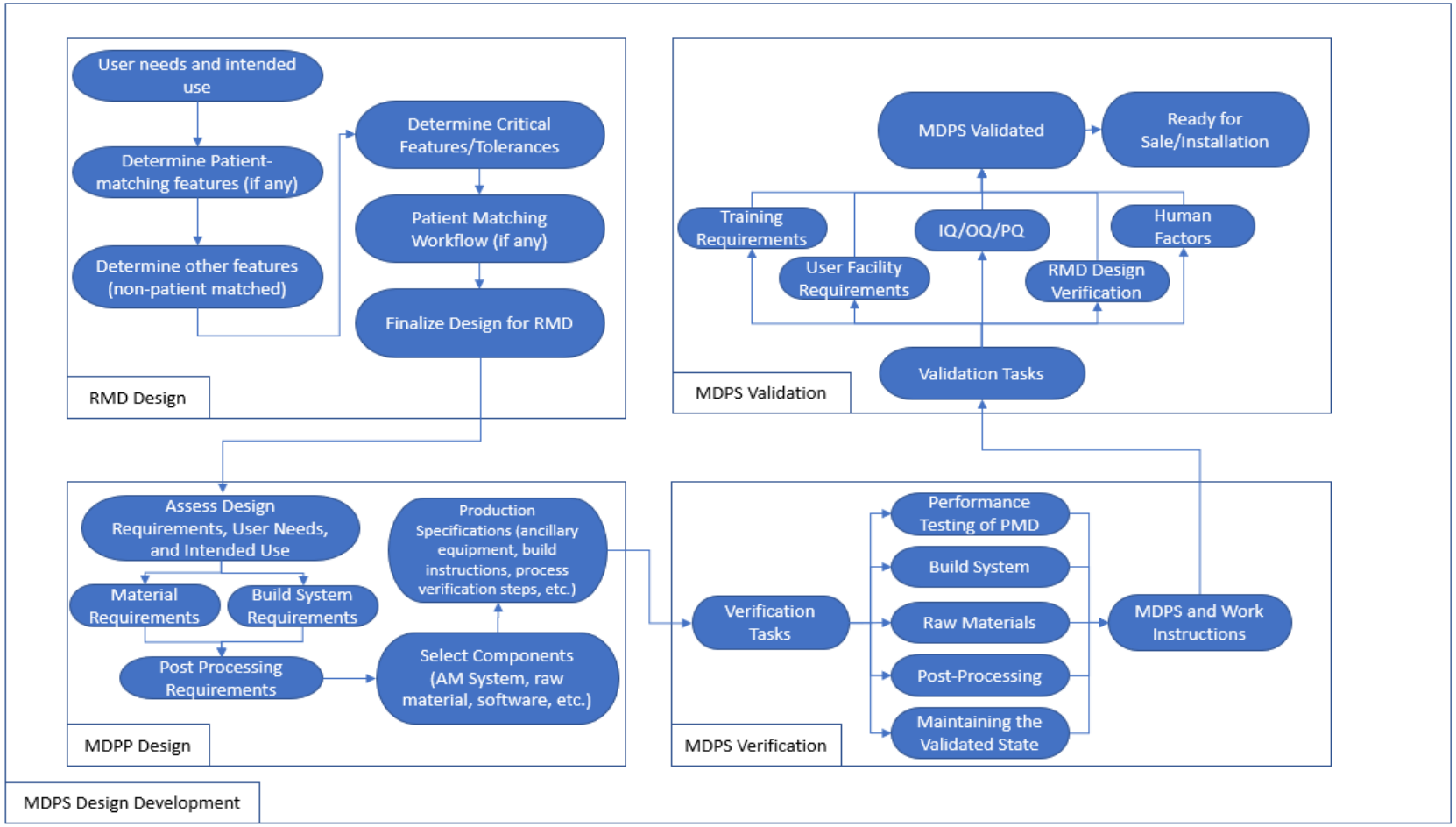
*** RMD – Resultant medical device**

- specific medical device that the MDPP produces using the operating instructions supplied by the MDPS manufaturer

→ MDPS의 classification, labelling 등 추가 개념 도입

PMD- Production Verification and Validation

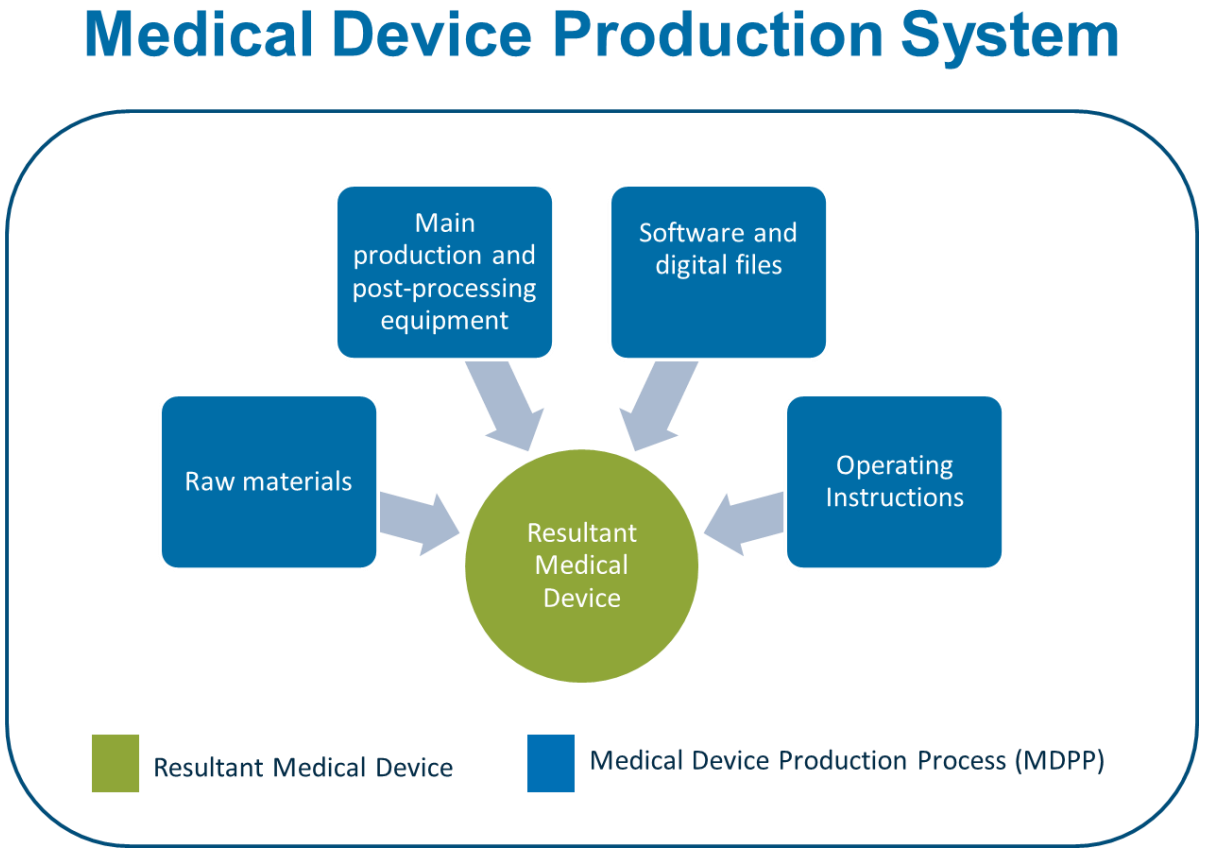
✓ Design development of MDPS



PMD- Regulatory Pathways(N58)

✓ 가이드라인 주요 개정 사항

* MDPS 개념 추가



가이드라인 제개정 향후 계획

- ✓ Deep dive meeting : 5th Aug. ~ 10th Aug.
- ✓ Final version Review (~End of Aug)
- ✓ Public consultation (60 days or 90 days)