

New VMF Templates and Release Dates

- V-A-OT: Opening a VMF (no data)
- V-C-AC: VMF supplement
- V-C-MC: VMF annual report
- V-C-MR: Response to letter

• June 2022

- July 2022
- July 2022
- July 2022



ADMS: VMFs

Supply Chain Roles
Labeler
Manufacturer
Other
Packager
Particle Size Reducer
Relabeler
Repackager
Secondary Packager
Sterilizer
Storer
Tester

Entity Types
Drug Product
Drug Substance
Excipient
Other
Intermediate

Operational Status
Active
Inactive
Withdrawn



ADMS: Submitting establishment information

- All establishment information
 - VMF originals (V-C-OT)
 - VMF annual updates (V-C-AC)

- Establishments related to the change
 - VMF supplements (V-C-MC)



ADMS: VMF Resources

CVM eSubmitter Resource Center:

https://www.fda.gov/industry/fda-esubmitter/cvm-esubmitter-resource-center

<u>CVM eSubmitter Master File Quick Guide</u> – This guide explains how to use the Master File book to store and reused master file information to support ADMS supply chain information.

Youtube playlist for webinars:

https://youtube.com/playlist?list=PLey4Qe-UxcxYpFaXMzdX3SfNdp38YxXV