

CDRH Guidance Prioritization

What does it mean and
how is it done?

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June 5, 2014

CDRH Guidance Priority List

CDRH maintains a list of guidance documents under active development.

- ▶ 87 guidance documents currently under development

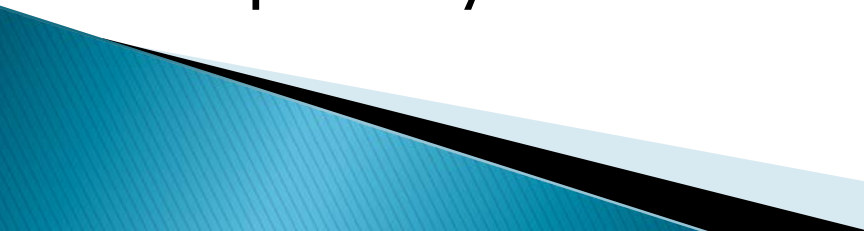
CDRH Guidance Priority List

CDRH also keeps a separate list bifurcating the list into prioritized and non-prioritized guidance documents.

- ▶ 31 Priority
- ▶ 56 Non-priority

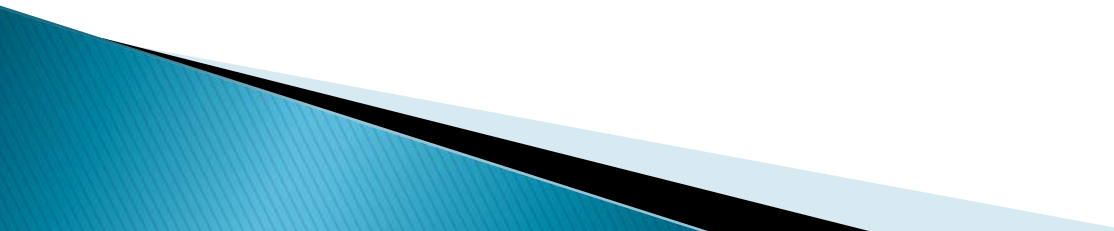
Prioritization Purpose

Communicates Center priorities to all CDRH staff

- All staff should be aware of top policy initiatives
 - Allows staff (in and out of CDRH) to appropriately prioritize work
 - Allows for more predictability on prioritized documents
 - Allows for greater intra-agency visibility on priority documents and initiatives
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Prioritization Purpose

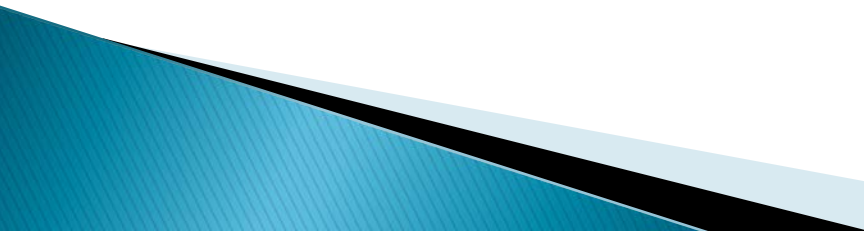
Does not prevent non-prioritized guidances from moving through the development process



Prioritization Process

- Annual process, managed within the Office of the Center Director
- The list can and is updated at any time
- As a new guidance development activity emerges, it is added to the list with a priority decision made at the discretion of the Deputy Center Director for Policy.

Annual Prioritization Process

- ▶ Data call for priority requests from all Offices
 - ▶ OCD collects info about each recommendation
 - ▶ Current development status
 - ▶ Office priority
 - ▶ Potential impact on stakeholders
 - ▶ OCD prepares draft priority list
 - ▶ Annual meeting with senior CDRH staff
 - ▶ Priority list distributed to Senior Staff and made available to all Center staff
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Effect of Prioritization

- ▶ Priority allocation of limited review and processing resources
 - CDRH development resources
 - OCC resources
 - FDA/OC resources
 - Expedited publishing requests

Effect of Prioritization

Setting internal guidance expectations

- ▶ All guidance documents follow a development process, but extra oversight can be afforded priority documents
 - Regular status updates
 - Setting internal milestone goals

Effect of Prioritization

Setting and communicating external guidance expectations

- ▶ Generally the Agency tries to stay away from public commitments on guidance issuance, but there are exceptions in limited circumstances
 - CDRH strategic priorities
 - Legislative commitments

Prioritized Guidances

- ▶ CDRH developed this list to reflect the Center's highest priority guidance documents expected to publish in fiscal year 2014 (October 1, 2013 – September 30, 2014). The CDRH Guidance Publication Priority List includes all documents that, as of October 1, 2013, have been identified as Center priorities for FY14.
- ▶ Guidance documents not included on the Center priority list should continue to move through the process of development, review, clearance, and publication.
 - Draft – 25 (10/1//13); 19, 7 issued 1 new (6/1/14)
 - Final – 18 (10/1/13); 12, 7 issued 1 new (6/1/14)

Non-Prioritized Guidances

CDRH developed this list to reflect additional guidance documents under development in fiscal year 2014. The list includes all documents that, as of October 1, 2013, Offices have identified for development in FY14. Additional needs may emerge; the Additional FY14 Guidance list may be revised throughout the year. For questions on relative priority please speak with your Office GGP representative.

- Draft – 35 (10/1//13); 44, 9 issued 16 new, 2 deleted (6/1/14)
- Final – 13 (10/1/13); 12, 6 issued, 5 new (6/1/14)

CDRH Fiscal Year 2014 (FY 2014) Proposed Guidance Development

- ▶ MDUFA III commitment, focus on issuance in FY2014 only
 - A list
 - Final 5 of 12
 - Draft 3 of 4
 - B List 0 of 6