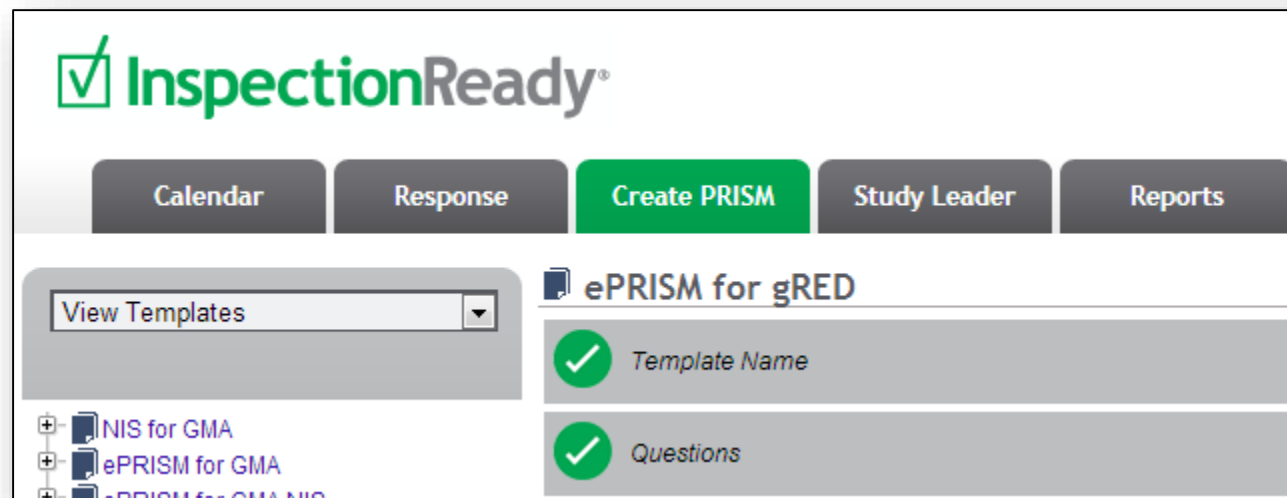


## Create PRISM Tab Questions Color Bar

This reference guide is an overview of the **Questions** color bar within the **Create PRISM** tab. The following process steps are covered within this document:

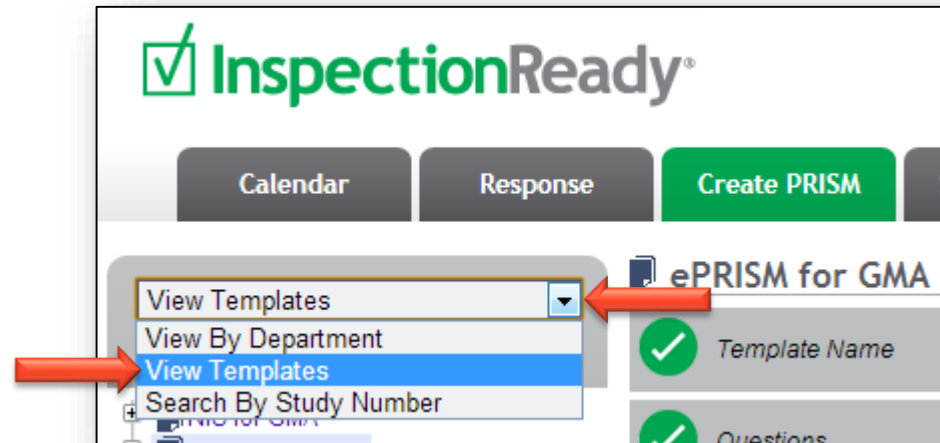
- ✓ Add new question
- ✓ Edit question



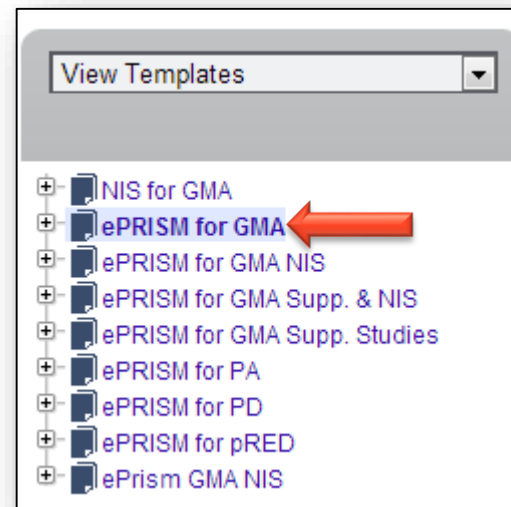
## Add New Question

### Add New Question

1. Select **View Templates**.



2. Select the [template](#) to add new question.



3. Click **Questions**.

The screenshot shows the InspectionReady dashboard. At the top, there are navigation buttons: Calendar, Response, Create PRISM (highlighted in green), Study Leader, and Reports. Below these is a 'View Templates' dropdown menu. On the left, there is a sidebar with expandable items: NIS for GMA, ePRISM for GMA, and ePRISM for GMA NIS. On the right, the 'ePRISM for gRED' section is visible, containing two items: 'Template Name' and 'Questions'. A red arrow points to the 'Questions' item.

4. Click [New](#).

The screenshot shows the 'Questions' page. At the top, there is a green checkmark icon and the text 'Questions'. Below this are links for 'Feedback', 'Help?', and 'Audit'. The main content is a table with the following columns: Section, Accountable Role, Anticipated Inspector Questions / Request for Information, Supporting Documentation, and a 'New' button. Below the table are search filters for Role, Inspector, and Documentz. The table contains one row with the following data:

Section	Accountable Role	Anticipated Inspector Questions / Request for Information	Supporting Documentation	
I	IML, ICTM	Determine the overall organization of the clinical research activities and monit...	Summary of clinical development plan/program for inspected molecule List of al...	3 No <a href="#">Edit</a>

5. Click **Section**.

**UPDATE QUESTION**

Section\* ?

Choose One

- Choose One
- I. Org & Pers
- II. Vendors
- III. Investigators
- IV. Monitors
- V. Monitoring
- VI. QA
- VII. Protocol Mngt
- VIII. Safety
- IX. Data Mngt
- X. TMF
- XI. Systems
- XII. IMP
- XIII. Samples
- XIV. Supporting Studies

Supporting Documentation\* ?

6. Enter **Accountable Role**.

**UPDATE QUESTION**

Section\* ?

I. Org & Pers

Accountable Role ?

7. Enter **Regulatory Reference**,  
**Anticipated Inspector Questions/Request for Information**, **Supporting Documentation**, and **Items To Be Considered**.



Regulatory Reference\* ?

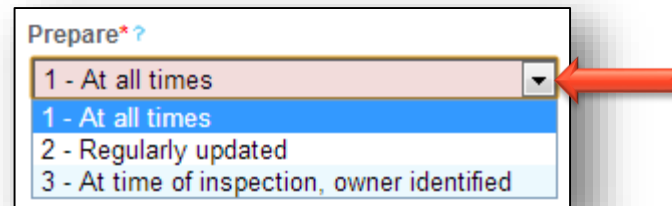
Anticipated Inspector Questions/Request for Information\* ?

Supporting Documentation\* ?

Items To Be Considered ?

8. Select **Prepare** value.

9. Click **Save Changes**.



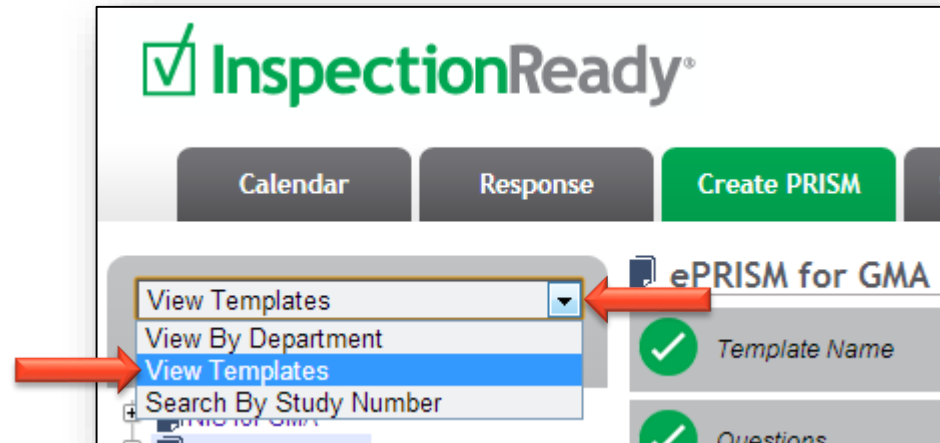
Prepare\* ?

- 1 - At all times
- 1 - At all times
- 2 - Regularly updated
- 3 - At time of inspection, owner identified

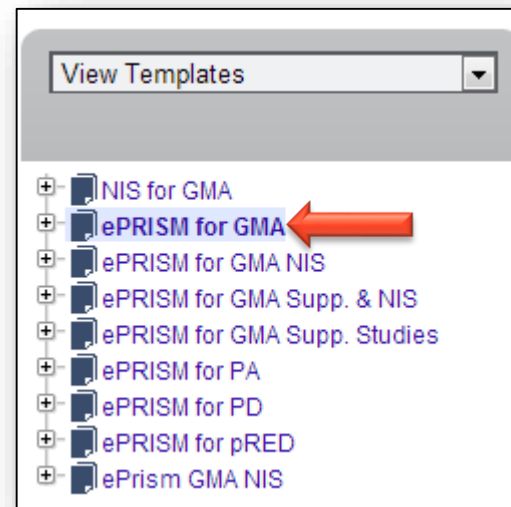
## Edit Question

### Edit Question

1. Select **View Templates**.



2. Select the [template](#) to edit question.



3. Click **Questions**.

The screenshot shows the InspectionReady dashboard. At the top, there are navigation buttons: 'Calendar', 'Response', 'Create PRISM' (highlighted in green), 'Study Leader', and 'Reports'. Below these is a 'View Templates' dropdown menu. To the right, there is a section titled 'ePRISM for gRED' with a list of templates. The first template is 'Template Name' and the second is 'Questions'. An orange arrow points to the 'Questions' template.

4. Click [Edit](#).

The screenshot shows the 'Questions' page. At the top, there is a 'Questions' header with a green checkmark icon and a '[hide] Questions' link. Below the header are links for 'Feedback', 'Help?', and 'Audit'. The main content is a table with the following columns: 'Section', 'Accountable Role', 'Anticipated Inspector Questions / Request for Information', 'Supporting Documentation', and 'Prepare CRO'. The table has a search bar and a 'Show All' dropdown. The first row of the table is highlighted, and an orange arrow points to the 'Edit' link in the 'Prepare CRO' column.

Section	Accountable Role	Anticipated Inspector Questions / Request for Information	Supporting Documentation	Prepare CRO
1	I	IML, ICTM	Determine the overall organization of the clinical research activities and monit...	Summary of clinical development plan/program for inspected molecule List of al... <a href="#">Edit</a>

5. Edit the desired **Question** fields.

6. Click **Save Changes**.

**Note:** Select **Delete Question** to remove a question from the template.

### UPDATE QUESTION

Section\* ?  
I. Org & Pers

Accountable Role ?  
IML, ICTM

Regulatory Reference\* ?  
BIMO III C1

Anticipated Inspector Questions/Request for Information\* ?  
Determine the overall organization of the clinical research activities and monitoring of the selected studies.

Supporting Documentation\* ?  
Summary of clinical development plan/program for inspected molecule  
List of all trials for the molecule (Development, IST, Registry, Partner/Collaborator trials)

Items To Be Considered ?  
The IML would e in a strong position to give an overview of the CDP / Medical Plan.  
List of all trials for the molecule (Development, IST, Registry, Partner/Collaborator trials): CTMS

Prepare\* ?  
3 - At time of inspection, owner identified

CRO Oversight ?  
 Yes

**Save Changes** ← **Delete Question**