Submission no. 9

Section 5: Good clinical practice requirements

1 Does the text in this section adequately explain what is required?

No

2 Are there other good clinical practice-related safety issues or safety concerns that you consider should be included in this section?

Yes

3 Comments or suggestions

Comments or suggestions on section 5:
5.3 Product specification - is this the C of A for the IP vials used to compound products or is it details of how the IP vials are used in compounding final product to be infused i.e. the compounding worksheet? Does the PI need to keep a copy or can this be delegated to pharmacy to be kept with their trial documentation?

The sponsor usually has C of A for IP. Does the new guideline recommend the sponsor supplies this to the PI or just that the PI has the C of A to be able to verify the IP meets approved specifications.

Is a C of A required for all IP whether used in compounding under GMP or a simple dispensing?

The PI should be stored as specified .....cannabidiol is B2 and currently in a lockable fridge abd more than 1 month dispensed and will be reclassified soon to RT - will reclassifications be covered by a statement about current legislation rather than current at time of publication of this new guideline.

Your details

1 Your details

Name and designation:
XXXXXXXXXXXXXXXXXXXX

Company/organisation name (if applicable):
Auckland District Health Board

Address:
XXXXXXXXXXXXXX
XXXXXXXXXXXXXX
XXXXXXXXXXXXXXX
XXXXXXXXXXX

Phone number:
XXXXXXXXXXXXXXX

Email address:
XXXXXXXXXXXXXXX

2 This submission is:

made on behalf of a group or organisation(s)

3 I am, or I represent an organisation, based in:

New Zealand

If you selected other, please specify:

4 I am, or I represent, a:

Health professional

If you selected health professional, please indicate your type of practice:
pharmacy

If you selected other, please specify:

Publishing submissions and privacy

1 Publishing submissions

You may publish this submission

2 Official Information Act responses

Remove my personal details from responses to Official Information Act requests

3 Commercially sensitive information

This submission does not contain commercially sensitive information

If your submission contains commercially sensitive information, please let us know where.: