

## **Navigating and Searching Within a GXPNOW eBook**

plus

**FAQs about GXPNOW contents, updates and annotations,  
ordering, privacy and access, and eBook customization**

(It's all actually really quite simple!)



# Navigating the eBooks is simple!

this frame is always visible to help you navigate and to remind you what eBook and section you are currently viewing

Navigating and searching eBook contents is simple!

The screenshot shows the GXP NOW eBook interface. At the top is a dark blue header with the GXP NOW logo. Below the header is a navigation bar with several buttons: 'See the Table of Contents', 'See The Search Bar', '(GCP-1) Good Clinical Practice (GCP) for Drug and Biologic Clinical Trials Conducted for FDA Consideration US Code of Federal Regulations Title 21: Food and Drugs Part 11—Electronic Records; Electronic Signatures', 'See/Add Notes or Highlights', and 'Home'. The main content area displays the following text: 'CFR Title 21: Food and Drugs', 'Chapter I: Food and Drug Administration, Department of Health and Human Services', 'Subchapter A: General', 'Part 11—Electronic Records; Electronic Signatures', 'Subpart A—General Provisions', '§11.1 Scope.', '§11.2 Implementation.', '§11.3 Definitions.', 'Subpart B—Electronic Records', '§11.10 Controls for closed systems.', '§11.30 Controls for open systems.', '§11.50 Signature manifestations.', '§11.70 Signature/record linking.', 'Subpart C—Electronic Signatures', '§11.100 General requirements.', '§11.200 Electronic signature components and controls.', '§11.300 Controls for identification codes/passwords.', 'AUTHORITY: 21 U.S.C. 321-393; 42 U.S.C. 262.', 'SOURCE: 62 FR 13464, Mar. 20, 1997, unless otherwise noted.', 'Subpart A—General Provisions', '§11.1 Scope.'

Annotations with red arrows point to various elements:

- 'opens/closes a TOC pane' points to the 'See the Table of Contents' button.
- 'opens/closes a key-word search pane' points to the 'See The Search Bar' button.
- 'opens/closes a pane displaying a subscriber's private/unique annotations' points to the 'See/Add Notes or Highlights' button.
- 'brings you back to the home/log-in page where you can switch titles' points to the 'Home' button.
- 'the scroll bar is always visible and navigates line-by-line through the entire document rather than jumping to one specific entry' points to the vertical scroll bar on the right side of the content area.
- 'each TOC entry is also a hyperlink that jumps right to that specific section or subsection' points to the 'Subpart A—General Provisions' entry in the table of contents.

# Searching for specific eBook content is easy too.

Navigating and searching eBook contents is simple!



(GMP-1) Current Good Manufacturing Practice (cGMP) for FDA-regulated Drug and Biologic Products Manufactured in the United States  
US Code of Federal Regulations Title 21: Food and Drugs  
Part 11—Electronic Records; Electronic Signatures

See the Table of Contents    See The Search Bar    See/Add Notes or Highlights    Home

CFR Title 21: Food and Drugs  
Chapter I: Food and Drug Administration, Department of Health and Human Services  
Subchapter A: General  
Part 11—Electronic Records; Electronic Signatures

## Subpart A—General Provisions

[§11.1 Scope.](#)

[§11.2 Implementation.](#)

[§11.3 Definitions.](#)

## Subpart B—Electronic Records

[§11.10 Controls for closed systems.](#)

[§11.30 Controls for open systems.](#)

[§11.50 Signature manifestations.](#)

[§11.70 Signature/record linking.](#)

## Subpart C—Electronic Signatures

[§11.100 General requirements.](#)

[§11.200 Electronic signature components and controls.](#)

[§11.300 Controls for identification codes/passwords.](#)

For broad searches, the index in each document's index is a hyperlink that takes you directly to that corresponding contents



# For more specific content searches, use the Table of Contents.

Navigating and searching eBook contents is simple!

click to show/hide the eBook's Table of Contents (TOC) pane

increase (+)  
decrease (-)  
index level

click on an  
entry to  
jump right  
to that  
specific  
section

Table of Contents Hide this window >

- (GCP-1) Good Clinical Practice (GCP) for Drug and Biologic Clinical Trials Conducted for FDA Consideration
  - + US Code of Federal Regulations Title 21: Food and Drugs
    - Part 11—Electronic Records; Electronic Signatures
      - Subpart A—General Provisions
      - Subpart B—Electronic Records
      - Subpart C—Electronic Signatures
    - + Part 50—Protection of Human Subjects
    - + Part 54—Financial Disclosure by Clinical Investigators
    - + Part 56—Institutional Review Boards
    - + Part 312—Investigational New Drug Application
    - + Part 314—Applications for FDA Approval to Market a New Drug
    - + Part 600—Biological Products: General
    - + Part 601—Licensing
    - + Part 610—General Biological Products Standards
    - + Part 660—Additional Standards for Diagnostic Substances for Laboratory Tests
    - + Part 1271—Human Cells, Tissues and Cellular and Tissue-based Products
  - + US Code of Federal Regulations Title 45: Public Welfare
  - + ICH Guidelines (as Included in The US Code of Federal Regulations)

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(GCP-1) Good Clinical Practice (GCP) for Drug and Biologic Clinical Trials Conducted for FDA Consideration  
US Code of Federal Regulations Title 21: Food and Drugs  
Part 11—Electronic Records; Electronic Signatures

Hide the Table of Contents See The Search Bar See/Add Notes or Highlights Home

### Subpart A—General Provisions

#### §11.1 Scope.

(a) The regulations in this part set forth the criteria under which the agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

(b) This part applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in agency regulations. This part also applies to electronic records submitted to the agency under requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in agency regulations. However, this part does not apply to paper records that are, or have been, transmitted by electronic means.

(c) Where electronic signatures and their associated electronic records meet the requirements of this part, the agency will consider the electronic signatures to be equivalent to full handwritten signatures, initials, and other general signings as required by agency regulations, unless specifically excepted by regulations effective on or after August 20, 1997.

(d) Electronic records that meet the requirements of this part may be used in lieu of paper records, in accordance with § 11.2, unless paper records are specifically required.

(e) Computer systems (including hardware and software), controls, and attendant documentation maintained under this part shall be readily available for, and subject to, FDA inspection.

(f) This part does not apply to records required to be established or maintained by §§ 1.326 through 1.368 of this chapter. Records that satisfy the requirements of part 1, subpart J of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

(g) This part does not apply to electronic signatures obtained under § 101.11(d) of this chapter.

(h) This part does not apply to electronic signatures obtained under § 101.8(d) of this chapter.

(i) This part does not apply to records required to be established or maintained by part 117 of this chapter. Records that satisfy the requirements of part 117 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

(j) This part does not apply to records required to be established or maintained by part 507 of this chapter. Records that satisfy the requirements of part 507 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

(k) This part does not apply to records required to be established or maintained by part 112 of this chapter. Records that satisfy the requirements of part 112 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

(l) This part does not apply to records required to be established or maintained by subpart L of part 1 of this chapter. Records that satisfy the requirements of subpart L of part 1 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

(m) This part does not apply to records required to be established or maintained by subpart M of part 1 of this chapter. Records that satisfy the requirements of subpart M of part 1 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

(n) This part does not apply to records required to be established or maintained by subpart O of part 1 of this chapter. Records that satisfy the requirements of subpart O of part 1 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

# Use the keyword search feature the narrowest search.

Navigating and searching eBook contents is simple!

enter all/part of a word/  
phrase to search; any/all  
matches in the open eBook

click here to  
show/hide the  
side Search Bar

click here to  
clear  
the search  
results from  
the screen  
when  
you're  
finished

search results  
also appear  
throughout the  
eBook chapters'  
text showing  
each specific  
entry as well

The screenshot displays the GXP NOW search interface. At the top, a search bar contains the word "clinical" and a "Search" button. Below the search bar, a sidebar on the left lists various regulatory topics, with "Part 50—Protection of Human Subjects" selected. The main content area shows search results for "clinical", including sections like "50.25 Elements of informed consent", "50.27 Documentation of informed consent", "Subpart C—[Reserved]", "Subpart D—Additional Safeguards For Children In Clinical Investigations", "50.50 IRB duties", "50.51 clinical investigations not involving greater than minimal risk", "50.52 clinical investigations involving greater than minimal risk but presenting the prospect of direct benefit to individual subjects", "50.53 clinical investigations involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subjects' disorder or condition", "50.54 clinical investigations not otherwise approvable that present an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of children", "50.55 Requirements for permission by parents or guardians and for assent by children", and "50.56 Wards". The word "clinical" is highlighted in red boxes in the search bar, the sidebar, and throughout the text of the search results. A "Clear Search" button is visible in the sidebar. Navigation buttons like "See the Table of Contents", "Hide The Search Bar", "See/Add Notes or Highlights", and "Home" are also present.

# Highlighting and/or Annotating eBook Text is also simple.

Navigating and searching eBook contents is simple!

click to show/hide notes or highlights pane while you're working

Hide Notes or Highlights

Home

Hide this window

Click and drag your cursor over the text you want to highlight or note.

Click on your name (below) to go to the dashboard/index of all your existing highlight/notes.

My Name 10/10/2022

(a) This part contains procedures and requirements governing the use of investigational new drugs, including procedures and requirements for the submission, [More](#)

My Name 10/10/2022

This part changed in 1996. Make sure you make other relevant changes

clicking on an annotation jumps directly to that corresponding section in the text

drag your cursor across whatever portion of the text you'd like to annotate or highlight

Annotations are automatically dated

Highlights/annotations can be edited and/or deleted any time

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(GCP-1) Good Clinical Practice (GCP) for Drug and Biologic Clinical Trials Conducted for FDA Consideration  
US Code of Federal Regulations Title 21: Food and Drugs  
Part 312—Investigational New Drug Application

§312.300 General.

§312.305 Requirements for all expanded access uses.

§312.310 Individual patients, including for emergency use.

§312.315 Intermediate-size patient populations.

§312.320 Treatment IND or treatment protocol.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360bbb, 371, 42 U.S.C. 262.  
SOURCE: 52 FR 8831, Mar. 19, 1987, unless otherwise noted.

Subpart A—General Provisions

§312.1 Scope.

(a) This part contains procedures and requirements governing the use of investigational new drugs, including procedures and requirements for the submission to, and review and Drug Administration of investigational new drug applications (INDs). An investigational new drug for which an IND is in effect in accordance with this part is exempt from the premarketing approval requirements that are otherwise applicable and may be shipped lawfully for the purpose of conducting clinical investigations of that drug.

(b) References in this part to regulations in the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

§312.2 Applicability.

(a) **Applicability.** Except as provided in this section, this part applies to all clinical investigations of products that are subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to the licensing provisions of the Public Health Service Act (58 Stat. 632, as amended (42 U.S.C. 201 et seq.)).

(b) **Exemptions.** (i) The clinical investigation of a drug product that is lawfully marketed in the United States is exempt from the requirements of this part if all the following apply:

(i) The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug;

(ii) if the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product;

(iii) The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.



# How content changes are displayed in the text.

Important Note: any annotation attached to text that has not changed stays anchored where you put it!

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The screenshot shows the GXP NOW website interface. At the top, there is a dark blue header with the GXP NOW logo. Below the header, there are navigation buttons: 'See The Table of Contents', 'See The Search Bar', '(GCP-2) Good Clinical Practice (GCP) for Medical Device Clinical Trials Conducted for FDA Consideration US Code of Federal Regulations Title 21: Food and Drugs', 'See/Add Notes or Highlights', and 'Home'. The main content area is titled 'Part 801—Labeling' and 'Subpart B—Labeling Requirements For Unique Device Identification'. The text includes sections for §801.20 and §801.30. Two annotations are present: a red box around the text '(1) A finished device manufactured and labeled prior to the compliance date established by FDA for §801.20 regarding the device. This exception expires with regard to a particular device 3 years after the compliance date established by FDA for the device.' and a green box around the text '(2) A class I device that FDA has by regulation exempted from the good manufacturing practice requirements of part 820 of this chapter, exclusive of any continuing requirement for recordkeeping under §820.180 and 820.198.' Red arrows point from the text to the boxes, with labels: 'old text being replaced is set-off by a red box' and 'new replacement text is set-off by a green box'.

subscribers are emailed alerts when changes are made

old text being replaced is set-off by a red box

new replacement text is set-off by a green box



## How is GXPNOW the *better mousetrap* than the regulations and guidance sources that are out there now?

GXPNOW monitors and continuously incorporates updates to critical pharma, biologic and medical device regulations, guidances and guidelines that have been issued by a wide variety of official sources into one place for subscribers.

Our unique eBook portal allows subscribers to overlay (and edit) their own personal notes and highlights to the books' text. Your personal annotations are visible only to you and only you can amend them. The key to GXPNOW is that when an eBook's content changes our proprietary software preserves and anchors your existing annotations in their original positions while we give you a window of time to review content changes, allowing you to adjust any annotations as you like. So, your book and your annotations are always current. Plus, we actively email subscribers to let them know that a regulation, guidance or guideline has changed; showing what the change(s) are and giving subscribers time to modify or add any existing personal annotations if necessary.

Plus, with GXPNOW eBooks, there is no shipping cost and subscription access is instant – anywhere in the world.





## Why should I pay for content that is available at no cost?

In two simple words: *accuracy* and *convenience*.

The vast majority of information on the Internet is not labeled with a posting date, nor is it *ever* updated or removed altogether - so what looks timely and accurate is probably not! The live calendar on the GXPNOW homepage reflects status of each eBooks' update status.

Additionally, GXPNOW's eBooks save you valuable time by aggregating regulations and guidances by topic from a number of sources and organized it into a searchable format where subscribers can privately annotate the content and access their subscription from any device with an Internet connection.

*Free* can, and is, often actually very expensive!

## Where does GXPNOW's source its eBook content?

Unless otherwise noted, we source all eBook content directly from publications issued or endorsed by "competent authorities" including the Food and Drug Administration (FDA) in the US and the European Medical Association (EMA) in the EU. GXPNOW eBook contents reflect original material including spelling and grammar errors.

(DGW-1) The Plain English Reference Guide is the only eBook that includes editorialized content.



## How often is the eBook content updated and how do I know about updates?

GXPNOW constantly monitors the content of every eBook, updating content in as close to real-time as possible. As soon as we incorporate changes into an eBook, subscribers are emailed an alert about those changes so they can make add new and/or edit any existing annotations they've made there and elsewhere.

## What happens to my existing annotations when an eBook's content changes?

Nothing, each subscribers' personal existing annotations stay exactly how and where they were entered. If a subscriber annotation is anchored to a place where the content has changed. They will receive advance notice from GXPNOW and will also have ample "overlap" time with both old and new content to to make any edits.

## Can I edit and/or delete my own annotations after I've made them?

Absolutely, you can edit, re-edit, delete, highlight and/or add to any of your notes any time from any connected device.

## Who can see the annotations I've made in eBook(s) that I've subscribed to?

No one but you. Access to your private annotations are linked to your individual login credentials so no one else can see or edit them.

## Can I add additional eBook titles to my existing subscription without having to create a new account?

Yes! Go through the normal subscription purchase process and at the "Checkout" step, check the "Returning customer?" box where you can use your existing account information [Click here to login](#) to add additional eBooks.

## What device(s) can I use to access my eBook subscription(s)?

Any connected device(s) — desktop, laptop, tablet, phone... eBooks are designed to automatically format themselves to fit any size screen and are fully functional and accessible on any connected device.

## Can anyone suggest additions or edits to existing eBook format or content?

Absolutely! We do this for you, so your input is priceless. We're always open to having a conversation around how we can improve any/all aspects of the GXPNOW experience. Please always feel free to contact us by text/phone at 1-267-888-7800 or by email at [hello@gxpnow.com](mailto:hello@gxpnow.com).

## Can GXPNOW customize its proprietary platform to create a private portal to include topics like training, SOPs, etc. without regulations and guidances?

Also absolutely! We can customize our proprietary platform to create a "private portal" that includes whatever information an organization needs to distribute and update in a controlled manner, and that can be administered in-house to allow certain users to access certain information in specific areas.

This has proven to be a great for ongoing training curricula, SOPs, study information, etc.

In addition to customizing content, private portals typically incorporate the host-organization's own branding and style-sheeting.



## What do I do if I forget my login or password?

Simple, your Log In ID is your email address. If you forget your password, go to the Log In tab on the homepage and click "[Forgot Password](#)" to reset it. Or you can always contact a live person at by email at [hello@gxpnow.com](mailto:hello@gxpnow.com) or by text/phone at 1-267-888-7800 if you're still having trouble.

## Can I share my subscription with a friend/colleague?

No. Your subscription, including your personal annotations are your own, and just as we don't share your information, we ask that you don't share ours. Subscriptions may be purchased for others via the homepage or by contacting us by telephone/text (1-267-888-7800) or by email [hello@gxpnow.com](mailto:hello@gxpnow.com).

## Can someone else order and pay for my and/or others' subscription(s)? How??

Yes; for example, a manager or administrator may order and pay for single or multiple individuals in their department or organization. In the cart during check-out, the person ordering will fill-in the name and email of which subscriber(s) will have access to which eBook(s). After check-out is complete the designated subscribers will individually receive an email asking them to create a unique log-in that only they will be privy to.

So, the easiest way to do this is have the individual who is paying for the subscription place the order, even if they are not going to be a subscriber themselves, since it is their payment information that will be required at check-out. Or you can always contact a live person at by email at [hello@gxpnow.com](mailto:hello@gxpnow.com) or text/phone at 1-267-888-7800 if you're having trouble.

## What forms of payment does GXPNOW accept? How fast can I expect delivery/access after payment?

- We accept all major credit cards via our web site.
- We accept other electronic payment forms like Venmo, Zelle, etc. by phone/text (1-267-888-7800) or email ([hello@gxpnow.com](mailto:hello@gxpnow.com)).
- We accept checks in \$US and purchase orders.
- With electronic payment, access to your subscription is immediate, anywhere in the world, any time! When we receive payment by check or purchase order, we will immediately notify you that your subscription access is available.

## Can I cancel my subscription for a refund?

Yes and no... Subscription(s) can be cancelled by the person who paid for it/them within five days of their order date for a full refund (via their original payment method). After that, unfortunately we cannot provide any refunds.

If you need a refund, please contact us by telephone/text (1-267-888-7800) or by email ([hello@gxpnow.com](mailto:hello@gxpnow.com)).

## What do I do if my email address or other contact information changes during my subscription?

It's important that we're able to reach you with content updates, etc. If your email and/or other contact information changes, please email us at [hello@gxpnow.com](mailto:hello@gxpnow.com) or call/text us at 1-267-888-7800 so we can update your records and keep in-touch.



## How long does my subscription run and will it automatically renew?

All subscriptions are active for one year from the order date. GXPNOW's default policy is to not auto-renew subscriptions; we will email you a reminder in time for you renew so you don't lose access to the regulations, guidance and guidelines, or the personal annotations you have made during your subscription.

## Does GXPNOW use cookies or sell, trade or share my personal information, annotations or search history?

In a word, "NO." We respect your privacy. For all the details, please see the GXPNOW's ["Terms of Use"](#).

## If I need help or have questions, can I speak with an actual live person?

*Absolutely!* Please contact us by phone/text at 1-267-888-7800 or by email at [hello@gxpnow.com](mailto:hello@gxpnow.com) with any questions, comments, suggestions, etc. We're a small organization so If we're not available when you originally make contact, please leave a message and a live person will be in-touch as soon as possible.

