

EU Good Manufacturing Practice  
**ANNEX 13**

Investigational Medicinal Products  
Articles 26-33  
Labeling Requirements Explained

## TABLE OF CONTENTS

What's the importance of Annex 13 Labeling Requirements?.....	3
Annex 13 Labeling Requirements Explained.....	4
General Principles .....	4
Primary vs. Secondary Packaging .....	4
Detailed Guidance of Annex 13 .....	5
Article 26 .....	5
Notes on Article 26.....	5
Article 27 .....	7
Notes on Article 27 .....	8
Article 28 .....	8
Notes on Article 28.....	9
Article 29 .....	10
Notes on Article 29.....	11
Article 30 .....	11
Notes on Article 30.....	12
Article 31 .....	12
Notes on Article 31 .....	12
Article 32 .....	13
Notes on Article 32.....	13
Article 33 .....	13
Notes on Article 33.....	14
Looking Ahead.....	15
References .....	15

## What's the Importance of Annex 13 Labeling Requirements?

Can you imagine working for months to ensure your clinical supply strategy is in place for your European studies, only to have them be delayed because labeling requirements were out of compliance, and the QP or the site(s) rejected the materials you wanted to use in a trial?



The European pharmaceutical market is expected to grow to 206 billion euros in 2022, making it an enticing market to companies worldwide.<sup>1</sup> It is also one of the most well-regulated regions that requires a thorough understanding of common challenges and pitfalls for initiating clinical studies. The European Union (EU) currently comprises 28 individual countries with approximately 22 official languages spoken. Sponsor companies looking to hold clinical studies in the EU must comply with set EU Directives and EU Good Manufacturing Practice (GMP) guidelines.

The purpose of this guide is to walk US-based clinical supply professionals through the labeling requirements laid out in Annex 13 of the EU GMP guidelines. This annex details guidance for Investigational Medicinal Products (IMPs), and this handbook will focus only on those Articles applicable to labeling requirements (Articles 26 to 33). For US pharmaceutical companies planning clinical trials in Europe, it is critical to comply with these labeling requirements so as not to experience any delays.

While most EU countries will accept the standard Annex 13 requirements for standard trials, there are some countries that have additional requirements. For example, some national authorities may require the inclusion of a trial number or a EudraCT number that is logged with the national authorities in a database.

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### ***Disclaimer:***

*Please note that this guidance does not give definitive information regarding the precise label details required for any trial that might be conducted in any or all EU Member States. For each specific trial, it is imperative that the sponsor ensures, with the guidance of knowledgeable regulatory affair experts and a trusted clinical packaging and labeling partner, that all regulatory and clinical requirements have been addressed for a particular trial. The label text will need to be submitted with each application to conduct a trial; however, approval of this by the authorities does not negate the responsibility of the sponsor to ensure that the labeling is correct.*

*Please also note that each country within the EU may have national regulatory and/or labeling requirements that go beyond the general requirements detailed in Annex 13 so it is important that confirmation of these is obtained.*

## Annex 13 Labeling Requirements Explained



Before providing additional guidance on the interpretation of Articles 26 to 33 in Annex 13, it might be helpful to first provide some general guidance regarding expectations and reasons for the requirements as stated. For all of these, it should be noted the scope is restricted to IMPs only. For any other medication used in a trial (e.g., escape medication), these are typically classed as non-IMPs or NIMPs and labeling of these does not generally have to comply with full Annex 13 requirements. Again, it is imperative that the sponsor checks what details are required for a specific trial.

### General Principles



The objective for specifying regulatory requirements for investigational medicinal products used in clinical trials is to help ensure:

- (i) Protection of the subjects involved
- (ii) Traceability of the IMP
- (iii) Patient compliance through proper use of the IMP
- (iv) Identification of the trial
- (v) Identification of the IMP (after emergency unblinding)
- (vi) Clear, thorough and accurate documentation of the trial

Samples of the label(s) attached to IMP containers form part of the essential documents required to support the conduct of a clinical trial. Each label must show compliance to applicable labeling regulations and the instructions must be appropriate for the trial subjects (i.e., clear dosing instructions). In all blinded trials, the labeling of IMPs must also protect the blinding.

For any unusual dosage form, presentation or packaging, you need to carefully consider how the requirements apply in each specific situation.

### Primary vs. Secondary Packaging



For clarity, the primary container or package is generally considered that which is in product contact. Therefore, any label on this would be a primary label, and labeling requirements for primary package/packaging refer to this label. The secondary package is generally considered that which encloses the primary container/package. Some examples are given below:

A glass vial is a primary container as it is in direct contact with the contents (medicinal product). If the vial is then placed into a carton containing one or more vials, this is the secondary package and the labeling requirements must comply with those for the secondary packaging. The term “outer” package is sometimes used, but if Annex 13 labeling requirements are specified, it is generally considered the same as the secondary package.

A blister strip or bottle containing solid dose forms would be the primary package, as in both cases the product is in direct contact with the container. If the strip is placed into a carton or wallet, these would be considered the secondary packaging. It is the same for any bottle or bottles placed into a carton and the carton then labeled.

The carton is generally considered secondary packaging and, when appropriate for a specific trial, the label applied must comply with the full Annex 13 requirements.

### Detailed Guidance Of Annex 13

Clinical labeling requirements are detailed in Annex 13 of the EU GMP Guide (Eudralex Volume IV of the Rules), Articles 26 – 33. Each of these Articles have been reprinted in full below, followed by detailed guidance. Please note that these Articles are not the same as the Articles found in the CT Directive.

#### Article 26

Labelling should comply with the requirements of Directive 2003/94/EC. The following information should be included on labels, unless its absence can be justified, e.g., use of a centralised electronic randomisation system:

- (a) Name, address and telephone number of the sponsor, contract research organisation or investigator (the main contact for information on the product, clinical trial and emergency unblinding);
- (b) Pharmaceutical dosage form, route of administration, quantity of dosage units, and in the case of open trials, the name/identifier and strength/potency;
- (c) The batch and/or code number to identify the contents and packaging operation;
- (d) A trial reference code allowing identification of the trial, site, investigator and sponsor, if not given elsewhere;
- (e) The trial subject identification number/treatment number and where relevant, the visit number;
- (f) The name of the investigator (if not included in (a) or (d));
- (g) Directions for use (reference may be made to a leaflet or other explanatory document intended for the trial subject or person administering the product);
- (h) “For Clinical Trial Use Only” or similar wording;
- (i) The storage conditions;
- (j) Period of use (use by date, expiry date or retest date as applicable), in month/year format and in a manner that avoids any ambiguity;
- (k) “Keep out of reach of children” except when the product is for use in trials where the product is not taken home by subjects.

#### Notes on Article 26

Labeling has to comply with the EU GMP Directive (2003/94/EC). This Directive states in Article 15 that “in the case of IMPs, labeling should be such as to ensure protection of the subject and traceability, to enable identification of the product and trial, and to facilitate proper use of the Investigational Medicinal Product.”<sup>2</sup> Labeling must also comply with Directive 2001/20/EC (Clinical Trials).<sup>3</sup> In Article 14 it specifies that

particulars are to appear in at least the official language(s) of the Member State on the outer packaging or, where there is no outer packaging, on the immediate packaging as detailed in the guidelines, namely Annex 13 of the EU GMP Guide Part I.<sup>4</sup>

It should be noted that both the outer (secondary) packaging and immediate (primary) container have to include the same extensive information on their labels if they may be separated during the conduct of the trial. Later in this guidance document, you will see that there is a partial exemption of the requirements allowed for small units/unit doses (such as ampoules, small vials, tablets and capsules).

Partial exemption of labeling requirements is allowed for small units or unit doses.

### **Taking Each Labeling Requirement In Turn:**

- (a) Name, address and telephone number of main contact: this information is important for the subject and/or their relatives/carers in case of any queries and if emergency unblinding is required (see Article 27 for exemption items including the address and telephone number). The name – typically of the sponsor, but could be the CRO or investigator (e.g., ABC Pharma) is always required.
- (b) Pharmaceutical dosage form: it is important that this is clear on the labels to identify the type of contents of the pack, and provide important information regarding route of administration. It is common to see phrases such as “For intravenous use only.” It is important to add the number of dosage units in each pack; for example, 21 tablets or 1 x 10ml vial. For open trials, the IMP label must state the product name and potency or strength as appropriate.
- (c) The batch and/or code number: this will be a unique code which in the relevant documentation will ensure full traceability to the batch(es) of product(s) that are in that pack. This trial batch or code number needs to differentiate between different packaging and assembly jobs that may be required for the same trial. This is important in case of any quality problems detected with one specific packaging job, so these packs can be identified and action taken as required. If it is a blinded study, unique randomized kit numbers will be used in conjunction with the batch/code number for traceability.
- (d) A trial reference code: this is required if not given elsewhere. This should allow (unique) identification (through reference) of the trial, site, investigator and sponsor. This is especially important if the same IMP may be used in different trials at the same time. It helps avoid confusion at every stage of the storage, distribution, receipt and use of any IMP. Please note, this code is not linked to any approval procedure by the authorities so it is important to have all the unique identifiers in it, otherwise it is possible that another organization chooses exactly the same reference code.
- (e) Trial subject identification/treatment/visit number as relevant: the information about trial subject identification number or treatment number is particularly important for blinded trials with more than one treatment. The number allows identification and traceability of the IMP as well as the subject that is treated with it. Where relevant, the visit number must also be added to the label. This may be required in blinded crossover design trials where the same subject receives IMP and comparator for example, or different dosages of the IMP in a specific sequence. This helps ensure correct documentation and tracking of the correct treatment scheme. The relevant trial subject identification/treatment/visit number may be added to the label (handwritten) at the time of dispense. Therefore, the label must be designed with an identified space to record the information.

- (f) Name of the investigator: if not already included elsewhere. This may not be required if it is already included in the main contact information or trial reference code.
- (g) Directions for use: these are necessary to ensure proper use of the IMP and are therefore intrinsically linked to patient safety. However, reference can be made to other explanatory documentation (e.g., a leaflet provided) to be used either by the subject or person administering the product. Directions for use need to be clear, concise and unambiguous. If required, any such leaflet provided may have illustrations to assist with correct use of the product.
- (h) “For clinical trial use only” or similar wording: as with trials conducted within the US, there needs to be clear labeling indicating that the IMP involved is not (yet) approved. It is also a clear message to anyone else seeing the package, in case of any issues/queries. This information should be in a prominent position on the label.
- (i) Storage conditions: these need to comply with generally approved storage condition statements such as “Store at 2-8°C in a refrigerator – do not freeze,” or “Store below 25°C and keep away from direct sunlight.”
- (j) Period of use: as trials have become more globalized, often the following is used to minimize any misunderstandings: MMM YYYY. For trials with sufficient stability data, it is customary to accept that if the label states a use-by date of JUN 2019, the trial medication has stability supporting its use until the last day of that month. For extremely short shelf-life IMPs, typically during early phase trials, it may be necessary to use the DD MMM YYYY notation. Please note this must not be confused with any “in-use” shelf life (e.g., a product must be used within 7 days after reconstitution).
- (k) Keep out of the reach of children: while this statement is correct, it should be noted that in a number of countries, the requirement and/or best practice for labeling of marketed products is “keep out of the sight and reach of children.” This can be added to the label if there is room (this is subject to national requirements).

Article 26 states that some exemption from these requirements may be allowed by some countries in the EU if a company uses a centralized electronic randomization system. However, not all authorities are aligned on this and, of course, any centralized electronic system will need to be validated before use.

SCP-6166, 100mg Capsules Batch No: XXX	Protocol:XXX-XXXX Expiration Date: MMM-YYYY
Investigator: _____	Subject ID: _____
50 capsules per bottle; For oral use. Take as directed by your doctor Store at 15°C – 25°C. For clinical trial use only. Keep out of reach of children. Sponsor Pharmaceuticals, 6166 Nancy Ridge Drive, San Diego CA, 92121, USA	

*Example label text following Article 26 requirements for an open-label study.*

## Article 27

The address and telephone number of the main contact for information on the product, clinical trial and for emergency unblinding need not appear on the label where the subject has been given a leaflet or card which provides these details and has been instructed to keep this in their possession at all times.

### Notes on Article 27

Main contact information: this must appear on the label as it may be required for emergency unblinding in the case of a serious issue. Annex 13 does allow for an exemption from having to include the address and telephone number if the subject will be given a leaflet or card with these details, and they have been instructed to keep this in their possession at all times. The name of the relevant organization must always appear on the label as a minimum. Again, the address and telephone number can be omitted from the label of an immediate (primary) container where this and the outer packaging (secondary) remain together throughout the clinical trial as well as on blisters or small packaging units (e.g., small ampoules). In all cases, the name of the relevant (main contact) organization must be included on each label. However, a sponsor may decide to include the full information on the label as this increases the chance of finding it quickly in the event of an emergency.

### Article 28

Particulars should appear in the official language(s) of the country in which the investigational medicinal product is to be used. The particulars listed in Article 26 should appear on the primary packaging and on the secondary packaging (except for the cases described in Articles 29 and 30). The requirements with respect to the contents of the label on the primary and outer packaging are summarised in Table 1. Other languages may be included.

Table 1: Summary Of Labelling Details (§26 To 30)

- a) name, address and telephone number of the sponsor, contract research organisation or investigator (the main contact for information on the product, clinical trial and emergency unblinding);
- (b) pharmaceutical dosage form, route of administration, quantity of dosage units, and in the case of open trials, the name/identifier and strength/potency;
- (c) the batch and/or code number to identify the contents and packaging operation;
- (d) a trial reference code allowing identification of the trial, site, investigator and sponsor if not given elsewhere;
- (e) the trial subject identification number/treatment number and where relevant, the visit number;
- (f) the name of the investigator (if not included in (a) or (d));
- (g) directions for use (reference may be made to a leaflet or other explanatory document intended for the trial subject or person administering the product);
- (h) “for clinical trial use only” or similar wording;
- (i) the storage conditions;
- (j) period of use (use-by date, expiry date or re-test date as applicable), in month/year format and in a manner that avoids any ambiguity;
- (k) “keep out of reach of children” except when the product is for use in trials where the product is not taken home by subjects.

**GENERAL CASE**

For both the primary and secondary packaging (§26)

Particulars a<sup>4</sup> to k

**PRIMARY PACKAGE**

Where primary and secondary packaging remain together throughout (§29)<sup>5</sup>

a<sup>6</sup> b<sup>7</sup> c d e

**PRIMARY PACKAGE**

Blisters or small packaging units (§30)<sup>5</sup>

a<sup>6</sup> b<sup>7,8</sup> c d e

- <sup>4</sup> The address and telephone number of the main contact for information on the product, clinical trial and for emergency unblinding need not appear on the label where the subject has been given a leaflet or card which provides these details and has been instructed to keep this in their possession at all times (§ 27).
- <sup>5</sup> When the outer packaging carries the particulars listed in Article 26.
- <sup>6</sup> The address and telephone number of the main contact for information on the product, clinical trial and for emergency unblinding need not be included.
- <sup>7</sup> Route of administration may be excluded for oral solid dose forms.
- <sup>8</sup> The pharmaceutical dosage form and quantity of dosage units may be omitted.

**Notes on Article 28**

It should be noted that there are currently (pre-Brexit) 28 member states comprising the European Union, plus another three countries in the EEA region (Norway, Iceland and Liechtenstein) which follow the EU rules. Between all these countries, well over 20 languages are spoken. In some countries,<sup>4</sup> The address and telephone number of the main contact for information on the product, clinical trial and for emergency unblinding need not appear on the label where the subject has been given a leaflet or card which provides these details and has been instructed to keep this in their possession at all times (§ 27).

- <sup>5</sup> When the outer packaging carries the particulars listed in Article 26.
- <sup>6</sup> The address and telephone number of the main contact for information on the product, clinical trial and for emergency unblinding need not be included.
- <sup>7</sup> Route of administration may be excluded for oral solid dose forms.
- <sup>8</sup> The pharmaceutical dosage form and quantity of dosage units may be omitted.

### Notes on Article 28

It should be noted that there are currently (pre-Brexit) 28 member states comprising the European Union, plus another three countries in the EEA region (Norway, Iceland and Liechtenstein) which follow the EU rules. Between all these countries, well over 20 languages are spoken. In some countries, for example Belgium, the labels may have to include German, French and Dutch; in others, two languages may be required on the labels. The national authorities will state what language(s) need to be printed on the labels.



Over 22 languages are spoken in the EEA region, which adheres to Annex 13 labeling requirements.

### Article 29

When the product is to be provided to the trial subject or to the person administering the medication within a primary package together with secondary packaging that is intended to remain together, and the secondary packaging carries the particulars listed in Paragraph 26, the following information shall be included on the label of the primary package (or any sealed dosing device that contains the primary packaging):

- (a) Name of sponsor, contract research organisation or investigator;
- (b) Pharmaceutical dosage form, route of administration (may be excluded for oral solid dose forms), quantity of dosage units and in the case of open label trials, the name/identifier and strength/potency;
- (c) Batch and/or code number to identify the contents and packaging operation;
- (d) A trial reference code allowing identification of the trial, site, investigator and sponsor if not given elsewhere;
- (e) The trial subject identification number/treatment number and where relevant, the visit number.

### Notes on Article 29

This details the minimum labeling requirements for the primary package, when, and only if the primary and secondary package are intended to remain together.

- (a) Name of sponsor: note that no address or contact details required.
- (b) Dosage form and route of administration (note the latter is not required for oral solid dose forms): note that the quantity of dosage units will be the number in that specific primary pack. Therefore, there may be a blister strip presented in a wallet and two of these wallets are placed in a carton. If the dose is 1 x day and each wallet provides 2 weeks medication, each wallet label would be printed with 14 x units and the outer carton printed with 28 x units (i.e., 2 x 14).
- (c) The batch or code number: this would normally be the same as that on the secondary package and it should ensure that full traceability is possible (i.e., batch(es) of products used in the packaging run and the specific packaging run undertaken).
- (d) A trial reference code: this is required if not given elsewhere. This should allow (unique) identification (through reference) of the trial, site, investigator and sponsor. This is especially important if the same IMP may be used in different trials at the same time. It helps avoid confusion at every stage of the storage, distribution, receipt and use of any IMP. Please note this code is not linked to any approval procedure by the authorities so it is important to have all the unique identifiers in it, otherwise it is possible that another organization chooses exactly the same reference code.
- (e) The trial subject identification number/treatment number and, where relevant, the visit number: the primary label must also include a trial subject identification number/treatment number and, where relevant, the visit number. It is not necessary for the trial subject identification number to be printed on the label, as long as there is a line for this information to be written in at time of use.

Sponsor Pharmaceuticals SCP-6166, 50 Capsules Batch No: XXX Protocol No: XX-XXX-XXX-XXX Trial Subject ID No.: _____
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*Example label text per minimal labeling requirements for the primary package if primary and secondary packages are to remain together, per Article 29.*

### Article 30

If the primary packaging takes the form of blister packs or small units such as ampoules on which the particulars required in Paragraph 26 cannot be displayed, secondary packaging should be provided bearing a label with those particulars. The primary packaging should nevertheless contain the following:

- (a) Name of sponsor, contract research organisation or investigator;
- (b) Route of administration (may be excluded for oral solid dose forms) and in the case of open label trials, the name/identifier and strength/potency;
- (c) Batch and/or code number to identify the contents and packaging operation;

- (d) A trial reference code allowing identification of the trial, site, investigator and sponsor if not given elsewhere;
- (e) The trial subject identification number/treatment number and where relevant, the visit number.

### Notes on Article 30

There is some relief from the full labeling requirements for blister packs (where each unit contained within cannot be labeled) or small units such as ampoules. In these cases, the full labeling requirements as detailed in Article 26 cannot practically be included on any label. Instead of the requirements (a) to (k), the requirements as detailed above of (a) to (e) are required on these labels. Note that in this case, the dosage form and number of dosage units is not required on the label. Sponsors often find that a flag label is required (i.e., one that wraps around the small container then has a larger portion that a label with this information on it can be affixed). This ensures the label is printed in large enough font size and can account for the requirement for two or more languages for certain countries.

Sponsor Pharmaceuticals Batch No: XXX Protocol No: XX-XXX-XXX-XXX Trial Subject ID No.: _____
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*Example blister pack label text per Article 30. Dosage form and number of dosage units are not required for blister packs or small units.*

### Article 31

Symbols or pictograms may be included to clarify certain information mentioned above. Additional information, warnings and/or handling instructions may be displayed.

### Notes on Article 31

Symbols and pictograms can be very helpful and aid patient compliance. One type frequently used includes a partial sun for morning, full sun for daytime and moon for night – visually aiding a patient when they need to take a dose three times a day at regular intervals. Another system frequently used is that of calendar packs where each day of the week is listed across the top of a blister wallet presentation helping patient compliance. Any reasonably well-known symbol or pictogram should be considered where they can assist.



MORNING



MIDDAY



EVENING



BEDTIME

*Example symbols and pictograms.*

### Article 32

For clinical trials with the characteristics identified in Article 14 of Directive 2001/20/EC, the following particulars should be added to the original container but should not obscure the original labelling:

- (i) Name of sponsor, contract research organisation or investigator;
- (ii) Trial reference code allowing identification of the trial site, investigator and trial subject.

### Notes on Article 32

This clause refers to clinical trials identified in a specific Article in Directive 2001/20/EC. Where the product to be used in a clinical trial has already been granted a marketing authorization in the Member State(s) where the study is being conducted and does not require any particular manufacturing or packaging processes, a label with only the following information must be added to the package. It also must not obscure the original labeling:

- (i) Name of sponsor, contract research organization or investigator.
- (ii) Trial reference code (which, through reference, allows for the identification of the specific trial site, investigator and trial subject).

In other words, if an open style trial is being conducted and a marketed product is not being further processed but will be supplied in its original container, there are two pieces of information that must go on that label.

Sponsor Pharmaceuticals  
Protocol No: XX-XXX-XXX-XXX

*Example blister pack label text per Article 30. Dosage form and number of dosage units are not required for blister packs or small units.*

### Article 33

If it becomes necessary to change the use-by date, an additional label should be affixed to the investigational medicinal product. This additional label should state the new use-by date and repeat the batch number. It may be superimposed on the old use-by date, but for quality control reasons, not on the original batch number. This operation should be performed at an appropriately authorised manufacturing site. However, when justified, it may be performed at the investigational site by or under the supervision of the clinical trial site pharmacist, or other healthcare professional in accordance with national regulations. Where this is not possible, it may be performed by the clinical trial monitor(s) who should be appropriately trained. The operation should be performed in accordance with GMP principles, specific and standard operating procedures and under contract, if applicable, and should be checked by a second person. This additional labelling should be properly documented in both the trial documentation and the batch records.

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### Notes on Article 33

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This Article covers the requirement to update the use-by or retest date on previously supplied packs typically as a result of new stability data becoming available, which extends the usable shelf-life of an investigational medicinal product or other product supplied in the trial. Where possible, sponsors should organize activities so that any placebo batch use-by date does not become the shortest date, therefore restricting the overall trial date.

The authorities would typically prefer any re-labeling activity (as it is a GMP manufacturing operation) to be performed at an appropriately authorized manufacturing site. However, this would often mean that product is shipped back to the clinical trials packaging/labeling site, new use-by/expiry date labels affixed and shipped back to the investigator site. For a number of logistical and timing reasons, this may not be practical so it is allowed (subject to any national authority restrictions) for this to happen at an investigational site by or under the supervision of a clinical trial pharmacist or other healthcare professional in accordance with national regulations. It also may be performed by the clinical trial monitor(s) if appropriately trained.

In other words, the authority's general ranking of preference is:

- 1) Return material to an approved packaging/labeling site for application of the update label (involves two shipments)
- 2) Update labels applied at site by, or under the supervision of, a CT pharmacist
- 3) Update labels applied at site by CT monitor who has been trained

In practical terms, although (1) is preferred, it is (2) and (3) that are used more often as ways to effectively and efficiently apply update labels.

Typically, the sponsor or original clinical trial packaging/labeling site will prepare a simple worksheet and supply the required number of labels. This may deliberately include an additional label so this can be affixed to the documentation used for the over-labeling operation. The site will be instructed to involve two people at minimum so one can act as the checker/verifier. The Annex is very specific about how this new label should be applied and what it can or cannot obscure on the original label. A sample label should be applied to the worksheet and all critical activities verified. All labels supplied must be accounted for. The paperwork should be returned to the sponsor and filed appropriately. There should be at least one SOP covering this operation; typically one at the sponsor organization and one at the investigator site where the update labeling will actually be performed. Quality personnel should be involved in ensuring this operation is well-managed and under good control. They should be informed of any discrepancies as soon as possible.

Annex 13 mentions a contract and in this case, a legal contract and/or service level agreement may be appropriate. It is also expected that there be a quality/technical agreement in place which details each party's responsibilities regarding any over-labeling operations to be performed.

## Looking Ahead

Things are set to change quite a bit in the European Union over the next few years. The CT Directive will be replaced by a Clinical Trials Regulation (536/2014), which will make a number of aspects of conducting trials in the EU much simpler.

This means that sponsor companies will only have to prepare one submission to hold clinical studies in EU countries. Today, one submission is required per country.

Annex 13 is being replaced by a new guideline on GMP for Investigational Medicinal Products. One major change is the inclusion of a requirement to print the expiry or “use-by” date on both the primary and secondary packaging. The inclusion of this new requirement caused much adverse comment from the industry and as a result it is expected this will be reviewed again once the Regulation is implemented.

The timelines for implementation have changed a number of times and it is currently expected that Regulation 536/2014 will become effective sometime during the second half of 2019.

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