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Title: <b>Pharmaceutical label, leaflet printer GMP Audit Checklist</b>				

COMPANY NAME AND ADDRESS:.....  
 AUDIT DATE(S).....  
 AUDITOR(S) (lead first): .....  
 SPECIALIST(S): .....

REQUIREMENT:	AUDIT OBSERVATIONS:
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**1. Roll Feed Labels**

- |  |                                |
|--|--------------------------------|
| 1.1 Does each product label have its own set of printing plates? (That is, there must not be plates that are common to different product labels)   | Comply: yes / no / not checked |
| 1.2 Is each printing plate an integral unit? (They must not be designed in such a way that part could fall out during printing leaving intact other sections that are still printing)        | Comply: yes / no / not checked |
| 1.3 Are printing plates, when made obsolete return to the client company for verification and destruction?   | Comply: yes / no / not checked |
| 1.4 Are labels print on a machine which applies all the colours in one pass through the machine?   | Comply: yes / no / not checked |
| 1.5 Is only one specific product label print at the one time on a stock roll? That is, "gang printing" must not take place.  | Comply: yes / no / not checked |
| 1.6 Are two or more product labels that use the same size cutter prevented from being processed as consecutive jobs on a machine?  | Comply: yes / no / not checked |
| 1.7 Are reject labels and labels not delivered for any reason cut or mutilated before disposal?  | Comply: yes / no / not checked |
| 1.8 Before the commencement of each different process operating, eg. printing and cutting, is an area clearance check undertake and record by operators before proceeding to the next state? | Comply: yes / no / not checked |
| 1.9 Are there appropriate control systems and secure staging areas use to help prevent mix-ups of labels and printing plates?  | Comply: yes / no / not checked |
| 1.10 Are labels removed from a roll prohibited from being replaced – the backing slip must be left blank?  | Comply: yes / no / not checked |
| 1.11 Are spoilt labels removed from rolls?   | Comply: yes / no / not checked |

- 1.12 Do rolls contain any splices? If a splice is absolutely necessary is it made using coloured tape and a flag must be inserted in the roll.  
Comply: yes / no / not checked
- 1.13 Is the number of labels on each roll being shown?  
Comply: yes / no / not checked
- 1.14 Does each product label artwork bear a "revision code" to indicate artwork revisions? Where possible, does each product label artwork include a unique bar code for individual label identification using appropriate equipment?  
Comply: yes / no / not checked
- 1.15 Where practical, are label design and dimensions vary to improve differentiation between otherwise similar labels?  
Comply: yes / no / not checked
- 1.16 Where, due to wear or damage, printing plates require remaking, is the client informed and the new plates verified?  
Comply: yes / no / not checked
- 1.17 Are clients allowed to audit the factory and procedures on request?  
Comply: yes / no / not checked

**2.Cut Labels**

- 2.1 Does each product label have its own set of printing plates? (There must not be plates that are capable of being used, or designed to be used with different products)  
Comply: yes / no / not checked
- 2.2 Is each printing plate an integral unit? (They must not be designed in such a way that part could fall out during printing leaving intact other sections that are still printing)  
Comply: yes / no / not checked
- 2.3 Are printing plates, when made obsolete, returned to the client for verification and destruction?  
Comply: yes / no / not checked
- 2.4 Is only one specific product label printed at a time on each sheet of stock paper in a run print? (That is, "gang printing" must not take place)  
Comply: yes / no / not checked
- 2.5 Are reject labels and labels not delivered for any reason cut or mutilated before disposal?  
Comply: yes / no / not checked
- 2.6 Before the commencement of each different process operating, eg. printing and cutting, is an area clearance check undertaken and recorded by operators?  
Comply: yes / no / not checked
- 2.7 Are appropriate control systems and secure staging areas used to help prevent mix-ups of labels and printing plates?  
Comply: yes / no / not checked
- 2.8 Is the number of labels in each bundle of cut labels shown?  
Comply: yes / no / not checked
- 2.9 Does each product label artwork bear a "revision code" to indicate artwork revisions,

and a unique edge bar code to highlight the presence of any foreign labels?

Comply: yes / no / not checked

2.10 Where practical, are label design and dimensions varied to improve differentiation between otherwise similar labels?

Comply: yes / no / not checked

2.11 Where, due to wear or damage, printing plates require remaking, is the client informed and the new plates verified?

Comply: yes / no / not checked

2.12 Is the first completed sheet off the printer retained uncut and delivered to the client company with the cut labels for inspection?

Comply: yes / no / not checked

2.13 Are clients allowed to audit the factory and procedures on request?

Comply: yes / no / not checked

**3. Carton Printing**

3.1 Does each product carton have its own set of printing plates? (There must not be plates that are common to different product cartons.

Comply: yes / no / not checked)

3.2 Is each printing plate an integral unit? (They must not be designed in such a way that part could fall out during printing leaving intact other sections that are still printing).

Comply: yes / no / not checked

3.3 Are printing plates, when made obsolete returned to the client company for verification and destruction?

Comply: yes / no / not checked

3.4 Is only one specific product carton print at the one sheet stock during a run? ("Gang printing" must not take place)

Comply: yes / no / not checked

3.5 Are two or more product cartons which use the same design cutter prevented from being in the factory at the same time?

Comply: yes / no / not checked

3.6 Are cartons printed on a machine which applies all the colours in one pass through the machine?

Comply: yes / no / not checked

3.7 Are reject cartons and cartons not delivered for any reason cut or mutilated before disposal?

Comply: yes / no / not checked

3.8 Before the commencement of each process operating, eg. Printing, cutting, gluing, assembly, is an area clearance check undertaken and recorded by operators before proceeding ?

Comply: yes / no / not checked

3.9 Are an appropriate control systems and secure staging areas used to help prevent mix-ups of printed cartons and printing plates?

Comply: yes / no / not checked

3.10 Is the first completed sheet off the machine retained uncut, and delivered to the client company with the cartons for inspection?

3.11 Does each product carton bear a "revision code" to indicate artwork revisions, and a unique bar code eg. edge bar code, to highlight the presence of any foreign carton by visual or other appropriate means?  
Comply: yes / no / not checked

3.12 When, due to wear or damage, printing plates or knife assemblies require remaking, is the client informed and the replacement items verified?  
Comply: yes / no / not checked

3.13 Are clients allowed to audit the factory and procedures on request?  
Comply: yes / no / not checked

**4. Tubes and Plastic Containers**

4.1 Does each product tube or container have its own set of printing plates? (there must not be plates that are common to different product tubes or containers)  
Comply: yes / no / not checked

4.2 Is each printing plate (or screen) an integral unit? (They must not be designed in such a way that part could fall out during printing leaving intact other sections that are still printing).  
Comply: yes / no / not checked

Are obsolete printing plates or screens returned to the client company for verification and destruction?  
Comply: yes / no / not checked

4.3 Were practical, is all printing applied on a machine which applies all the colours in one pass through the machine?  
Comply: yes / no / not checked

4.4 Are two tubes or containers of the same size but for different products prevented from running as consecutive jobs on any machine?  
Comply: yes / no / not checked

4.5 Are procedures such that foreign tubes or containers cannot be mixed with product tubes or containers of the same size?  
Comply: yes / no / not checked

4.7 Are tubes and containers supplied in new shipping outers? If this is not practicable are re-used containers inspected before use to ensure there is no foreign tube or container in them, all old labels removed or defaced and new labels applied?  
Comply: yes / no / not checked

4.8 Do container product artwork bear a "revision code" to indicate artwork revisions?  
Comply: yes / no / not checked

4.9 Are there appropriate area clearance checks and secure staging areas to help prevent mix-ups between different product tubes and containers?  
Comply: yes / no / not checked

4.10 Where, due to wear or damage, printing plates require remaking, is the client informed and the new plates or screens verified?  
Comply: yes / no / not checked

4.11 Are clients allowed to audit the factory and procedures on request?  
Comply: yes / no / not checked

**5. Foil Printing**

5.1 Does each product component have its own set of printing plates? ( there must not be plates that are common to different product components)

Comply: yes / no / not checked

5.2 Is each printing plate an integral unit?  
(They must not be designed in such a way that part could fall out during printing leaving intact other sections that are still printing)

Comply: yes / no / not checked

5.3 Is foil printing done on a machine which applies all the colours in one pass through the machine?

Comply: yes / no / not checked

5.4 Is only one product artwork printed across the width of each original roll of foil during a print run?

Comply: yes / no / not checked

5.5 Are two or more product foils slit to the same size width prevented from being processed as consecutive jobs on slitting or re-rolling machine?

Comply: yes / no / not checked

5.6 Is slitting, inspection, re-rolling and packing for dispatch of printed foil for any product completed before slitting is started for any other printed foil?

Comply: yes / no / not checked

5.7 Is reject foil cut or mutilated before disposal?

Comply: yes / no / not checked

5.8 Is the use of splices in rolls prohibited? If a splice is absolutely necessary is it made using coloured tape and a flag must be inserted in the roll?

Comply: yes / no / not checked

5.9 Is the use of reject or foreign printed foil to start the winding operation of rolls prohibited?

Comply: yes / no / not checked

5.10 Is unprinted or spoiled foil prohibited from remaining on any finished printed rolls?

Comply: yes / no / not checked

5.11 Is there an appropriate area clearance check and are secure staging areas employed to help prevent mix-ups between different product foils and printing plates?

Comply: yes / no / not checked

5.12 Where, due to wear or damage, printing plates requiring remaking, is the client informed and the new plates verified?

Comply: yes / no / not checked

5.13 Does each product label artwork bear a "revision code" to indicate artwork revisions?

Comply: yes / no / not checked

5.14 Are clients allowed to audit the factory and procedures on request?

Comply: yes / no / not checked

**6. Leaflet Printing**

6.1 Does each product leaflet have its own set of printing plates? (there must not be plates that are common to different product labels.)

Comply: yes / no / not checked

6.2 Is each printing plate an integral unit?  
(They must not be designed in such a way that part could fall out during printing leaving intact other

sections that are still printing).

6.3 Where practical, are leaflets printed on a machine which applies all the colours in one pass through the machine?

Comply: yes / no / not checked

6.4 Is only one specific product leaflet printed on the one sheet stock during a run? (gang printing must not take place.)

Comply: yes / no / not checked

6.5 Are two or more product leaflets which use the same size sheet stock, prevented from being processed as consecutive jobs on any machine?

Comply: yes / no / not checked

6.6 Are guillotining, folding, bundling and packing for dispatch of any leaflet completed before guillotining is started for any other leaflet?

Comply: yes / no / not checked

6.7 Are reject leaflets cut or mutilated before disposal?

Comply: yes / no / not checked

6.8 Are an appropriate area clearance checks and secure staging areas employed to help prevent mix-ups between different product leaflets?

Comply: yes / no / not checked

6.9 Does each product leaflet artwork bear a "revision code" to indicate artwork revisions and a unique edge bar code for highlight the presence of a foreign leaflet?

Comply: yes / no / not checked

6.10 Where, due to wear or damage, printing plates require remaking, is the client informed and the new plates verified?

Comply: yes / no / not checked

6.11 Where practical, are leaflet colour, design and dimensions varied to improve differentiation between otherwise similar leaflets?

Comply: yes / no / not checked

6.12 Is the first completed sheet off the printer Retained uncut and delivered to the client with the leaflets for inspection?

Comply: yes / no / not checked

6.13 Are clients allowed to audit the factory and procedures on request?

Comply: yes / no / not checked

Comply: yes / no / not checked

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