

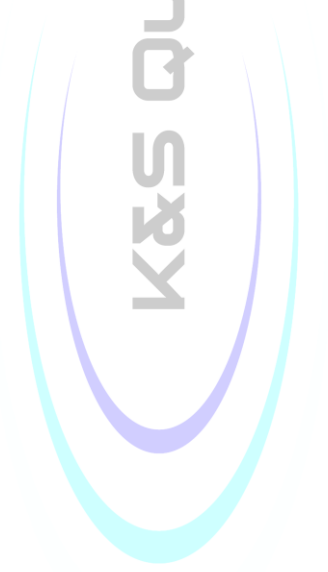
# Design & Development Process Based Audit By K&S Quality Associates

[www.QualityAssociates.org](http://www.QualityAssociates.org)

	<b>General Process Questions</b> (You may want to answer these questions after or while the specific questions starting at #23 are answered)	(N)Nonconformance (OFI)Opportunity for Improvement (S)Satisfactory	N/A	N/E
01	Is there a process flow diagram that adequately describes the inputs, outputs, responsibilities, resources, measurement point, and other requirement of the process?			
02	Does the Quality Manual properly address all the requirements of this section of the Standard?			
03	Are the documents required for this process controlled according to the requirements given in section 4.2.3 of the Standard?			
04	Are records created by this process controlled according to the requirements given in section 4.2.4 of the standard?			
05	Has management demonstrated an involvement in this process by the communication of a quality policy and objectives to the employees involved in this process?			
06	Is there evidence that management has reviewed this process during the management review meetings?			
<b>Objective evidence assessed / Observations / Comments / N/A explanation</b>				



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13	Is all measuring equipment (if any) used in this process calibrated in accordance with written procedures and the requirements of the standard?			
14	Does the organization conduct internal audits of this process at planned intervals to determine whether the process is effective and meets the requirements of the standard?			
15	Does the organization apply suitable methods for monitoring and, where applicable, measurement of this quality management system processes?			
16	Do these methods demonstrate the ability of the processes to achieve planned results?			
17	When planned results are not achieved, is correction and corrective action taken, as appropriate, to ensure conformity of the product?			
<b>Objective evidence assessed / Observations / Comments / N/A explanation</b>				
				

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18	In the event of process nonconformity, does the organization: <ul style="list-style-type: none"> <li>a) take appropriate action to correct the nonconforming process?</li> <li>b) evaluate whether the process nonconformity has resulted in product nonconformity?</li> <li>c) identify and control the nonconforming product in accordance with clause 8.3?</li> </ul>			
19	Does the organization determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of this process and to evaluate where continual improvement of the effectiveness of this process can be made?			
21	Are corrective actions relevant to this process utilized and verified for effectiveness?			
22	Are preventive actions relevant to this process utilized and verified for effectiveness?			
<b>Objective evidence assessed / Observations / Comments / N/A explanation</b>				



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	<b>Process Specific Questions</b>	(N)Nonconformance (OFI)Opportunity for Improvement (S)Satisfactory	N/A	N/E
<b>29</b>	<b>7.3.2</b> Are product input requirements determined and records maintained?			
<b>30</b>	Do the D&D inputs include: a) functional and performance requirements b) applicable statutory and regulatory requirements c) information derived from previous designs d) other essential D&D requirements			
<b>31</b>	Are the inputs reviewed for adequacy?			
<b>32</b>	<b>7.3.3</b> Are outputs in a suitable form for verification against the inputs and are they approved prior to release?			
<b>33</b>	Do D&D outputs: a) meet the input requirements b) provide appropriate information for purchasing, production, and service c) contain or reference product acceptance criteria d) specify product characteristics e) <b><i>specify critical items, including any key characteristics and specific actions to be taken</i></b>			
<b>Objective evidence assessed / Observations / Comments / N/A explanation</b>				

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	<b>Process Specific Questions</b>	(N)Nonconformance (OFI)Opportunity for Improvement (S)Satisfactory	N/A	N/E
<b>34</b>	<b><i>Do outputs define the data required for identification, manufacturing and inspecting including:</i></b> <ul style="list-style-type: none"> <li>- <b><i>drawings, part lists, and specifications</i></b></li> <li>- <b><i>material, process, manufacturing, and assembly data</i></b></li> </ul>			
<b>35</b>	<b>7.3.4</b> Are D&D reviews performed to: a) evaluate the ability of the results to meet requirements b) identify any problems and propose actions c) <b><i>authorize progression to the next stage</i></b>			
<b>36</b>	Does the participants in reviews include representatives from all functions concerned with the D&D stage(s) being reviewed?			
<b>37</b>	Are records of reviews and actions maintained?			
<b>38</b>	<b>7.3.5</b> Are verifications performed in accordance with planned arrangements?			
<b>39</b>	Are records of verifications and actions maintained?			
<b>Objective evidence assessed / Observations / Comments / N/A explanation</b>				

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	<b>Process Specific Questions</b>	(N)Nonconformance (OFI)Opportunity for Improvement (S)Satisfactory	N/A	N/E
<b>40</b>	<b>7.3.6</b> Are validations performed in accordance with planned arrangements?			
<b>41</b>	Are records of validations and actions maintained?			
<b>42</b>	<b>7.3.6.1</b> <i>Are verification and validation tests are planned, controlled, reviewed, and documented to ensure and/or prove the following:</i> <ul style="list-style-type: none"> <li>a) <i>test plans identify the tested product, resources used, define test objectives and conditions, parameters recorded, and acceptance criteria</i></li> <li>b) <i>test procedures describe the method of operation, test performance, and record of the results</i></li> <li>c) <i>correct configuration of the product for test</i></li> <li>d) <i>requirements of the test plan/procedures followed</i></li> <li>e) <i>acceptance criteria are met</i></li> </ul>			
<b>43</b>	<b>7.3.6.2</b> <i>Do reports, calculations, test results, etc. demonstrate product definition and meet the specified requirements for all operational conditions?</i>			
<b>Objective evidence assessed / Observations / Comments / N/A explanation</b>				

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	<b>Process Specific Questions</b>	(N)Nonconformance (OFI)Opportunity for Improvement (S)Satisfactory	N/A	N/E
<b>44</b>	<b>7.3.7</b> Are D&D changes identified and records maintained?			
<b>45</b>	Are changes are reviewed, verified, validated, and approved before implementation?			
<b>46</b>	Are records of the change reviews and any actions maintained?			
<b>47</b>	<i>Are D&amp;D changes controlled in accordance with the configuration management process?</i>			
<b>Objective evidence assessed / Observations / Comments / N/A explanation</b>				

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**As your system matures you may want to develop questions specific to any documented procedures/work instructions relating directly to this Process:**

**Procedure/WI #:**

**Question #:**

**Question:**

**Objective evidence assessed / Observations / Comments / N/A explanation:**

**Procedure/WI #:**

**Question #:**

**Question:**

**Objective evidence assessed / Observations / Comments / N/A explanation:**

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**Procedure/WI #:**

**Question #:**

**Question:**

**Conforming:**

**Minor:**

**Opportunity For Improvement:**

**Objective evidence assessed / Observations / Comments / N/A explanation:**

**Procedure/WI #:**

**Question #:**

**Question:**

**Objective evidence assessed / Observations / Comments / N/A explanation:**

# Process Based Audit By K&S Quality Associates

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**Procedure/WI #:**

**Question #:**

**Question:**

**Conforming:**

**Minor:**

**Opportunity For Improvement:**

**Objective evidence assessed / Observations / Comments / N/A explanation:**

**Procedure/WI #:**

**Question #:**

**Question:**

**Objective evidence assessed / Observations / Comments / N/A explanation:**

## Process Performance Evaluation

Minor Findings: \_\_\_\_\_ OFI's: \_\_\_\_\_ Total Findings: \_\_\_\_\_

Is this process meeting set objectives & Targets (Explain)?

### Process Evaluation:

1. Process is effectively implemented, planned results are achieved:
2. Process is implemented, planned results aren't achieved but appropriate actions are being taken:
3. Process is not effective, planned results aren't achieved and appropriate actions are not being taken:

Additional Notes:

Auditor: \_\_\_\_\_ Date: \_\_\_\_\_

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