Signatures, Initials, and Stamps

Many sections of QSR create records, which usually require a signature and a date. The assumption in QSR, is that this is a "handwritten signature", as opposed to electronic signature. In particular, when FDA wrote QSR, their position on electronic signatures had not matured to today's level of understanding.

This article does not consider electronic signatures. Instead, it looks at variations of the "handwritten signature" *e.g.*, initials and stamps. For an issue with QSR, three places provide useful information: the regulation, the preamble, and warning letters.

The Preamble

We start with the preamble, since it provides specific information, using a search function, for signatures, stamps, and initials:

	QSR Preamble Section
Stamp	94, 150
Initial	150
Signature	94, 150

Section 94 cites comments on the proposed §820.40(a). One comment suggests replacing the term "signature" with the term "identification" to allow electronic signatures. Similarly, other comments suggested changing the term to "signatures or stamps".

In the response, FDA says that under QSR, the term "signature" will permit the use of whatever electronic means the agency determines is the equivalent of a handwritten signature.

Additionally, FDA has not added the term "or stamps" but says that stamps could be acceptable:

- If the manufacturer has a formal procedure
- The procedure addresses the issues raised by electronic signatures
- The procedure addresses the control of stamps
- The procedure ensures the stamp is, in fact, the user's signature.

Section 150 cites a comment on §820.80(d) that says that signatures should not be the only method to identify the person responsible for release; FDA should allow the use of inspection stamps and initials.

In the response, FDA said that it is important that the person responsible for release personally document and date the release. This could include inspection stamps as long as the control follows the methods described for §820.40. Notice that the preamble does not address the use of initials. Presumably, initials that identify the person responsible would be acceptable.

QSR

Given the preamble discussion, this section cites the relevant portion, related to signatures, of the regulations discussed. Presumably, any other place in QSR that requires a signature would fall under the same conditions.

§820.40(a) Document controls – Document approval and distribution
The approval, including the date and signature of the individual(s) approving the document, shall be documented.

§820.40(b) Document controls – Document changes
Change records shall include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and when the change becomes effective.

§820.80(d)(3) & (d)(4) Receiving, in-process, and finished device acceptance – Final acceptance activities
Finished devices shall not be released for distribution until the release is authorized by the signature of a designated individual(s) and the authorization is dated.

Warning Letters
One of the areas to explore is Warning Letters. There is value in understanding how FDA Investigators apply the QSR Requirements. For these two sections, none of the warning letters objects to using initials and only cites conditions where a required signature or date is missing.

Gooten Innolife Corporation July 16, 2012
Failure to adequately establish and maintain document control procedures, as required by 21 CFR §820.40.

Specifically, there are no procedures that address the use of signature stamps in lieu of a handwritten signature. For example, a signature stamp was used to document approval of CAPA reports; however, these stamps are not controlled. On March 7, 2012, signature stamps were observed lying on the unattended desks of the Sales Manager and Production Manager in the shared office area.

The response indicates that the Document Control Procedure was revised to provide for proper and controlled use of the personal signature stamp to prevent misuse.

Rossmax International Ltd. March 28, 2008
Failure to establish and maintain adequate procedures to control all documents, specifically, to include the document approval date and signature of approving individual, as required by 21 CFR §820.40(a).

For example, your Quality Manuals at Rossmax Taiwan and Rossmax China were lacking the approval signatures and dates by firm management.

We have reviewed your response and have concluded that it is inadequate because you use ink stamps instead of original signatures by the approving individual but lack a written procedure on how the stamps are to be used and controlled. Please provide a revised document controls procedure that addresses the use of ink stamps.

Rossmax International Ltd. May 27, 2008
You provided a summary of your intention to revise the document controls procedure to include the use of stamps for document review and approval. This is not adequate to satisfy the requirements of 21 CFR §820.40, Document Controls. Please provide the procedure that addresses the use of ink stamps for document review and approval.

Olympus Terumo Biomaterials Corporation - Mishima Factory February 25, 2010
Failure to establish and maintain adequate procedures to control all documents and to designate an individual(s) to review for adequacy and approve prior to issuance all documents established to meet the requirements of this part. The approval, including the date and signature of the individual(s) approving the document, shall be documented, as required by 21 CFR §820.40(a).

For example, there are no written procedures to control stamps that are used by employees and management as signatures. There is no one responsible for issuing, receiving, or destroying stamps that are no longer in use.

We have reviewed your response and have concluded that it is inadequate because the procedures provided do not appear to define "seal" which appears be a personal signature stamp that is used for document review and approval.