Tips for Getting Started: Your Quality Management System (QMS) – Paper-Based Systems

- Preparing Documents
  - Thoroughly review and finalize documents by making necessary edits.
  - For Operational docs or Batch Records, dry run them before approving.
  - It will be easier to make changes prior to approval. After approval, changes will need to be tracked.
  - Avoid letting perfection prevent forward movement. Starting is essential, and the Change Control process exists to guide and refine as you go.
- Approving Documents
  - Create the first Change Order to begin the approval process. Follow your Change Control procedure.
  - Include the document(s) you are ready to approve.
    - Approve, train, use.
    - Once signed they need to be trained on and then used.
    - Don't want to ignore your own procedures.
    - Repeat with additional SOPs at a manageable pace.
  - Print each document.
  - Circulate to necessary department heads.
  - Sign/date.
- Document Storage/Access
  - Scan/create PDF of signed copy.
    - Upload and organize electronic folders similar to binders, see below.
    - Password protect forms, MMRs, logs, etc.
  - Keep original paper copy in binders.
  - Suggested Binders
    - Change Requests
    - SOPs
      - Quality
      - Materials
      - Labels
      - Etc.
    - Each Supplier
    - Each RM
    - Each Product's Batch Records
    - CAPAs
    - Non-compliances
    - Complaints
    - Etc.

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- Other Tips
    - Assign ownership early. Designate a QMS Champion to drive progress.
    - First time using new batch records, use the new draft and the original. Your original will be your actual documentation. Revise the draft until it's ready to be approved, trained on and then used.
    - Align leadership. Top management commitment determines success.
    - Follow your newly implemented procedures.
    - If GMP Certification is the goal, an auditor will want to see about three months of documentation using your QMS.
- Timeline

Phase	Focus
Months 1-3	Review and Approve SOPs, staff training, supplier qualification, adopt specs, MMRs
Months 4-6	Internal audits, continuous improvement, supplier audits, management review, prepare for GMP Certification
Total: ~6–12 months to achieve a functional, compliant QMS	