Privacy laws, FDA Regulations, and Evaluation pertaining to software Reading List

Mandatory Readings:

- For general background on HIPAA read:
  http://www.hhs.gov/ocr/privacy/hipaa/understanding/index.html

  (Optionally) explore the various sections, (mandatory) read the summaries of privacy and security:
  http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf

  http://www.hhs.gov/ocr/privacy/hipaa/understanding/srsummary.html

- Read about the HITECH Act of 2009, an update on the enforcement of HIPAA, at:
  http://www.hhs.gov/ocr/privacy/hipaa/administrative/enforcementrule/hitechenforcementifr.html

- Review the FDA's document on Medical Device Data Systems:
  http://www.gpo.gov/fdsys/pkg/FR-2011-02-15/pdf/2011-3321.pdf

- Read the FDA principles of software validation:
  http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm085281.htm

- Skim the European Union data sharing policies:
  http://ec.europa.eu/justice/newsroom/data-protection/news/120125_en.htm
  http://europa.eu/rapid/press-release_MEMO-14-60_en.htm

Optional readings:

- Read about the ISO 9000 standard for software evaluation:
  http://www.iso.org/iso/home/standards/management-standards/iso_9000.htm

- Life's a Breach, Part II: Omnibus Rule Revises What Constitutes a Breach under the HIPAA/HITECH Breach Notification Requirements
  http://www.alston.com/Files/Publication/2f74e6ac-abac-4cfc-8a7c-a5f6950d825f/Presentation/PublicationAttachment/a33a888a-fcea-4ba0-a9f8-ae1466d2242a/Lifes-a-breach.pdf

- Whitepaper on software validation (PDF)
  from: http://www.klocwork.com/resources/white-paper/software-verification-medical-devices

- Joanne Kumekawa's article on Health Information Privacy Protection: Crisis or Common Sense?
  http://www.nursingworld.org/MainMenuCategories/ANAMarketplace/ANAPeriodicals/OJIN/TableofContents/Volume62001/No3Sept01/PrivacyProtectionCrisis.asp

- Troubling Trends in Scientific Software Use
  http://www.sciencemag.org.liboff.ohsu.edu/content/340/6134/814.full.pdf

- Privacy Act of 1974
  http://www.justice.gov/opcl/1974privacyact-overview.htm

- FDA warning letter to 23 and me
  http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm376296.htm
  Related news article:
  http://www.genomeweb.com/clinical-genomics/fda-tells-23andme-halt-marketing-personal-genome-service (login required)

- Pacemaker software
  http://www.theregister.co.uk/2010/07/27/buggy_pacemaker_code/

- Bloodbank Software
  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=2379545