



**CRO'S CHECKLIST**

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# **Outsourcing Necropsy, Histology, & Pathology Services**



You have an anxious sponsor waiting for a pathology report or prepared microscope slides. Workloads are high and you don't have the staff to get the work done on time and on budget. What do you do?

Outsourcing necropsy, histology, and pathology services continues to increase as CROs strive to maximize their resources, increase their productivity, and expand their capabilities without expanding their workforce. Many organizations have come to see that outsourcing can seamlessly offer the same quality of work for prices competitive enough to be less expensive than internal operations.

There are many variables to consider when searching for a laboratory to outsource your study to. Ultimately, your goal is to find a research partner who can get the work you need done right, on time, and on budget. Use this outsourcing checklist as a guide to help you determine the qualifications of each contract laboratory and find the service provider you need.

# SCIENTIFIC AND TECHNICAL EXPERTISE

Locating a histopathology service provider with the scientific and technical expertise to handle the unique requirements of your study is priority number one. There are many reputable laboratories offering necropsy, histology, and/or pathology services. However, finding the research partner with the expertise and flexibility to handle the special needs of your study without major glitches is challenging. Here's what you'll need to know.

## What services do they offer that can assist you?

### NECROPSY / PROSECTION

- Are prosectors available to perform necropsy services on-site at your facility?
  - If so, at what cost?
  - How many prosectors will it take to finish the necropsy?
- When necropsy is performed on site, do they provide their own Standard Operating Procedures (SOPs) and materials?
- Do they have an ACVP Veterinary Pathologist who can oversee the necropsy?
- Do their prosectors weigh organs at the time of necropsy?
- Do their prosectors draw blood at the time of necropsy?

### HISTOLOGY

- Do they work on small and large animal studies?
- How many Good Laboratory Practices (GLP) studies do they work on in a given year?
- Do they audit 100% of the data for a GLP study?
- Are they familiar with processing all the tissues in your protocol or study design?
- Along with H&E staining, do they offer special staining?
- Can they handle the timeline *without* sacrificing quality?
- Has the lab been audited by the Food and Drug Administration (FDA)?
  - If so, what was the outcome(s) of the audit?
  - Did they receive a Form 483?
  - Did they receive a warning letter?
  - Were any objectionable conditions noted?

### IMMUNOHISTOCHEMISTRY

- Do they offer both brightfield and fluorescence?
- Manual or automated?
- What antibodies are available?
- Can protocols be optimized for your specific antibody?

### MORPHOMETRY / IMAGE ANALYSIS

- What software do they use?
- Do they have an on-site morphometrist?

### WHOLE MICROSCOPE SLIDE SCANNING

- What magnifications are offered?
- How can you access your images?

### PATHOLOGY

- Can they send a sample pathology report for your perusal?
- How long before a draft report will be submitted?
- How long before an audited final report will be submitted?
- Do they offer annotated photomicrographs?
- Do they offer peer review services?

## Are their Veterinary Pathologists ACVP board-certified?

- How many do they have on staff?
- What pathology software do they use for capturing data?
- Are their reports SEND ready?

## What are the unique interests, skills and/or accomplishments of each pathologist on site?

- Is there someone with the experience to oversee a necropsy?
- Is there someone with experience specific to your study?
  - Toxicologic pathology?
  - Carcinogenicity studies?
  - Wound healing models?
  - Reproductive pathology?
  - Others as needed?
- Are Bios, CVs, or Training Files available for review?

## What are the roles and responsibilities of the leaders in their organization?

- Will they share their organizational chart?
- Who will be the Principal Investigator(s) for our study?
- Who will serve as Test Site Management for our study?

## What is the background and experience of their histology/necropsy technicians?

- How much experience do they have working in a GLP environment?
- Do they have experience with the prosection of small and large animals?
- Are they cross-trained to process specimens from various species?
- Are Bios, CVs, or Training Files available for review?
- How many technicians do they employ?

# REGULATORY COMPLIANCE AND QUALITY ASSURANCE

To be successful, your study must be conducted in a manner that produces reliable data and complies with any and all applicable regulatory requirements. These regulating bodies may differ depending on the phase of your study and where the testing is being performed. However, if you intend to submit study data to the FDA, at the very least, you'll want to ensure compliance with GLPs.

## Is there documented evidence of successful FDA audits?

- Yes
- No

## Do they perform a Critical Phase Inspection (CPI) for each GLP study?

- Yes
- No

## Is there documented evidence of current staff training in GLPs?

- Yes
- No

## Are corrective action plans in place to address identified issues?

- Yes
- No

## Are there SOPs in place to govern all study-related tasks?

- Are they up to date and reflect current operations?
- Is there documented evidence of staff training on each procedure?

## Is there an in-house Quality Assurance department?

- Do they ensure SOPs are being followed?
- Do they ensure operations are regulatory compliant?
- Do they audit 100% of all data?
- Do they audit company facilities annually?
- Do they audit vendors?

# CUSTOMER SERVICE

Finding a caring and responsive histopathology service provider who understands your needs and works to deliver on your expectations is a key component to a cohesive outsourcing relationship. Checking in with client references is one way to get insight into how satisfied other customers are with the service and how satisfied you may be should you choose to work with a particular contract laboratory. However, if you pay attention and ask the right questions, you'll increase your chances of finding the information you need to make a good decision.

## Upon initial contact, do they listen carefully to your needs and talk through your study requirements?

- Yes
- No

## When checking customer references, do they report issues with timeliness or quality?

- Are prepared slides and/or pathology reports delivered within the specified time frame?
- Have there been issues with lost slides or documents?
- Is documentation neat and orderly?
- Are they happy with the overall presentation of slides?
  - Are slides labeled clearly?
  - Is the tissue placement consistently good?
  - Is the staining of the slides consistent and crisp?
  - Is tissue accountability high?
- Are they happy with the overall pathology report?
  - Is the data submitted in a clear, concise manner?
  - Was the pathology team responsive to your needs?

## Are they willing to assist with study design and protocol development?

- Yes
- No

## Do they propose services, timelines, and budgets that meet your needs?

- Yes
- No

## Are they able and willing to modify services and/or protocols to meet your needs?

- Yes
- No

## Do they offer flexible line item pricing for a la carte services so you only pay for what you need?

- Yes
- No

## What kind of transportation options are available?

- FedEx/UPS?
- Courier?

## Are there procedures in place to ensure the safe transport of wet tissue, paraffin blocks, slides, and documents?

- Is there an Exit Inventory containing study information and an accurate description of the package contents?
- Are transportation temperatures controlled?
  - Are there options for ambient, refrigerated, or frozen transportation?

## Do they offer archiving services?

- What type of storage options do they offer?
  - Ambient (room temperature)?
  - Refrigerated?
  - Frozen?
- Does the storage facility monitor access to study materials?
- Is the temperature and humidity of the storage facility controlled?
- Is there an automatic backup generator to provide power in case of shortages?
- Is there a fire suppression system to prevent the loss and damage of study materials due to fire?
  - Is the fire suppression system waterless to prevent damage to documents, digital media, and tissues?
- Is 24-hour study material retrieval available to allow shipment or auditing at any time?

As CROs endeavor to do more with less, outsourcing necropsy, histology, and pathology services has increasingly become a common option. There is a lot to consider when searching for a contract histopathology laboratory who can meet your needs. However, using this checklist will help you identify laboratories capable of handling the unique needs of your study.

